

US3422101 (Prod: Vanderbilt University Medical Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:32:16

All time stamps listed in this document are displayed in GMT

US3422101

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

---

Participant ID

US3422101

---

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

---

---

US3422101

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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

US3422101

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Date of Birth (MMM yyyy)	(b) (6) 1985
Age	35
Age Units	YEARS
Age (Derived)	35
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" 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

US3422101

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Date of Informed Consent ( <i>dd MMM yyyy</i> )	25 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" 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

US3422101

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

---

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

---

US3422101

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

---

Were any significant conditions reported?

Yes ☒

No ☐

---

US3422101

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Mar 2021 21:40:49

Generated On: 09 Jun 2021 17:32:16

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3422101

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Mar 2021 21:40:49

Generated On: 09 Jun 2021 17:32:16

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

US3422101

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 18 Mar 2021 21:40:49

Generated On: 09 Jun 2021 17:32:16

Condition	BIPOLAR DISORDER II
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

US3422101

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Mar 2021 21:40:49

Generated On: 09 Jun 2021 17:32:16

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

US3422101

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Mar 2021 21:40:49

Generated On: 09 Jun 2021 17:32:16

Condition	PILONIDAL CYST
Start date (dd MMM yyyy)	UN DEC 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)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3422101

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 18 Mar 2021 21:40:49

Generated On: 09 Jun 2021 17:32:16

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3422101

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	25 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	09:21 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 09:21
Height ( <i>xxx.x</i> )	70 in
Weight ( <i>xxx.x</i> )	165 lb
BMI ( <i>xxx.x</i> )	23.72454 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3422101

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 AUG 2020

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

US3422101

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

---

**Occupational Risk**

---

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☐

---

**Specify**

---

**Location and Living Circumstances Risk (check all that apply)**

---

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

---



US3422101

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

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

US3422101

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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

US3422101

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

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

What was the participant's randomization number? 108078

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Height	ND - Not Done
Weight	ND - Not Done

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	09:21 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 09:21
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	10:22 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 10:22
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3422101

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 AUG 2020

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

US3422101

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 09:52 (24 HR)

Treatment Date and Time (derived) 25 AUG 2020 09:52

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



US3422101

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 AUG 2020
Collection time (00:00-23:59)	09:25 (24 HR)
Collection date and time (derived)	25 AUG 2020 09:25

US3422101

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Collection date (dd MMM yyyy)			25 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:23	25 AUG 2020 09:23
Nasopharyngeal Swab 2	No		

US3422101

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

25 AUG 2020 10:26

PC Open Date & Time

25 AUG 2020 10:12

PC Close Date & Time

25 AUG 2020 12:42

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.9 °F

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

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

PC Time Stamp	25 AUG 2020 14:37
PC Open Date & Time	25 AUG 2020 13:37
PC Close Date & Time	26 AUG 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 17:13

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 12:45

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

28 AUG 2020 12:46

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59



US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 09:07

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 09:40

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 09:26

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

**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

25 AUG 2020 10:27

PC Open Date & Time

25 AUG 2020 10:12

PC Close Date & Time

25 AUG 2020 12:42

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 14:40

PC Open Date & Time

25 AUG 2020 13:37

PC Close Date & Time

26 AUG 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 17:15

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 12:46

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 12:47

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59



US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 09:07

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 09:41

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 09:27

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 10:27
PC Open Date & Time	25 AUG 2020 10:12
PC Close Date & Time	25 AUG 2020 12:42

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 14:40
PC Open Date & Time	25 AUG 2020 13:37
PC Close Date & Time	26 AUG 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

47 of 2667

EAB) (1725)



US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:32:16

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 17:16
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:32:16

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 2667

EAB) (1725)

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:32:16

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 12:46
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 2667

EAB) (1725)

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:32:16

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 12:48
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:32:16

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

53 of 2667

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:32:16

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 09:08
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:32:16

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 2667

EAB) (1725)



US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:32:16

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 09:42
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:32:16

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 2667

EAB) (1725)

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:32:16

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 09:27
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 09 Jun 2021 17:32:16

**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 02 SEP 2020 17:59

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 09 Jun 2021 17:32:16

**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

03 SEP 2020 12:05

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 09 Jun 2021 17:32:16

**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

04 SEP 2020 15:51

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:32:16

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time Stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59



US3422101

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 17:32:16

**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

02 SEP 2020 17:59

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:32:16

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:32:16

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	02 SEP 2020 18:00
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3422101

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 17:32:16

<b>TIMEPOINT</b>	DAY 11
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 SEP 2020 15:51
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3422101

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3422101

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422101

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3422101

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3422101

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3422101

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422101

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

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

US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

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)	22 SEP 2020
Time of assessment (00:00-23:59)	07:58 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 07:58
Temperature (xxx.x)	098.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	079 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	088 mmHg
Diastolic Blood Pressure units	MMHG

US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

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)	22 SEP 2020
Time of assessment (00:00-23:59)	09:09 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 09:09
Temperature (xxx.x)	097.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	074 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	074 mmHg
Diastolic Blood Pressure units	MMHG

US3422101

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3422101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 22 SEP 2020

What was the treatment time? (00:00-23:59) 08:39 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 08:39

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

US3422101

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 SEP 2020

Collection time (00:00-23:59)

08:01 (24 HR)

Collection date and time (derived)

22 SEP 2020 08:01



US3422101

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:59	22 SEP 2020 07:59
Nasopharyngeal Swab 2	No		

US3422101

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 09:19

PC Open Date & Time

22 SEP 2020 08:59

PC Close Date & Time

22 SEP 2020 11:29

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

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

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

PC Time Stamp 22 SEP 2020 18:17

PC Open Date & Time 22 SEP 2020 12:24

PC Close Date & Time 23 SEP 2020 11:59

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.8 °F
Was any <b>MEDICATION TAKEN</b> 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 <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	23 SEP 2020 13:11
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:32:16

---

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 13:22

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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 SEP 2020 15:14

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 21:26

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59



US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:32:16

---

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.0 °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

27 SEP 2020 15:48

---

PC Open Date & Time

27 SEP 2020 12:00

---

PC Close Date & Time

28 SEP 2020 11:59

---

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 15:48

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 09:20

PC Open Date & Time

22 SEP 2020 08:59

PC Close Date & Time

22 SEP 2020 11:29

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 18:17

PC Open Date & Time

22 SEP 2020 12:24

PC Close Date & Time

23 SEP 2020 11:59

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 13:11

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 13:22

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 15:15

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 21:26

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59



US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 15:49

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 15:49

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 09:20
PC Open Date & Time	22 SEP 2020 08:59
PC Close Date & Time	22 SEP 2020 11:29

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

- None ☐
- No interference with activity ☒
- Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐
- Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

- None ☐
- No interference with activity ☒
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

- None ☐
- No interference with activity ☒
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

- None ☒
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

- None ☒
- No interference with activity or  
1-2 episodes/24 hours ☐
- Some interference with activity  
or >2 episodes/24 hours ☐
- Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

- None ☒
- No interference with activity ☐
- Some interference with activity  
not requiring medical attention ☐
- Prevents daily activity and  
requires medical attention ☐

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 18:18
PC Open Date & Time	22 SEP 2020 12:24
PC Close Date & Time	23 SEP 2020 11:59

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☒

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

102 of 2667

EAB) (1725)

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:32:16

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 13:12
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59



US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:32:16

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 13:23
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

106 of 2667

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:32:16

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 15:15
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:32:16

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:32:16

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 21:26
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:32:16

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

110 of 2667

EAB) (1725)

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:32:16

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 15:49
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59



US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

112 of 2667

EAB) (1725)

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:32:16

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 15:49
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3422101

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3422101

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422101

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3422101

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422101

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3422101

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3422101

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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

US3422101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 19:57:32

Generated On: 09 Jun 2021 17:32:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	16 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	9:15 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 9:15
Temperature ( <i>xxx.x</i> )	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	75 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3422101

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

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.*

US3422101

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 OCT 2020
Collection time (00:00-23:59)	9:31 (24 HR)
Collection date and time (derived)	16 OCT 2020 9:31

US3422101

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:57:00

Generated On: 09 Jun 2021 17:32:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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

25 OCT 2020 18:17:58

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3422101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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	01 NOV 2020 04:51:45
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3422101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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 <input type="radio"/> Yes <input checked="" 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"/>
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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	08 NOV 2020 11:41:26
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 09:50:56

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 11:06:37
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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

03 DEC 2020 13:54:35

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 13:15:15
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 06:52:21
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 DEC 2020 04:52:34
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 09:46:42

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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

08 JAN 2021 09:12:08

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 14:05:31
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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

22 JAN 2021 19:32:57

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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

30 JAN 2021 10:06:41

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 08:17:47

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 10:18:43

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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	18 FEB 2021 11:51:16
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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 <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	26 FEB 2021 02:29:39
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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	04 MAR 2021 06:55:03
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 14:16:38
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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

20 MAR 2021 12:01:50

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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

29 MAR 2021 09:46:39

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 16:37:00

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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

08 APR 2021 06:55:49

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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"/>
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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 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"/>
Date and time of submission	15 APR 2021 09:17:53
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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

22 APR 2021 06:48:18

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

<b>TIMEPOINT</b>	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 APR 2021 09:15:02
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

06 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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 <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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 MAY 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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="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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

---

20 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

24 MAY 2021 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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 <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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

---

27 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

31 MAY 2021 23:59

---



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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 <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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

03 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUN 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

21 JUN 2021 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 306

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

24 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

---



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JUL 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUL 2021 23:59



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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="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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 AUG 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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="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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

05 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

19 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

---



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

02 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

16 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

---



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

23 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

30 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2021 23:59



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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="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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 432

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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 <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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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="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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 NOV 2021 23:59



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

18 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

---

<a href="#">Patient Cloud Open Date &amp; Time</a>	25 NOV 2021 00:01
--	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	29 NOV 2021 23:59
---	-------------------

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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 <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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 DEC 2021 23:59



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 DEC 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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°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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2021 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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

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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

06 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

---



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

20 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 523

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

---

27 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

31 JAN 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

03 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

---



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

10 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

---

24 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

28 FEB 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

03 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

---



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

---

10 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

14 MAR 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

21 MAR 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

---

24 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

28 MAR 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 586

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

---

31 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

04 APR 2022 23:59

---



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 APR 2022 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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="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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 APR 2022 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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="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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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="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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

05 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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 <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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

12 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 635

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

---

19 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

23 MAY 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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 <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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

---

26 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

30 MAY 2022 23:59

---



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

TIMEPOINT

DAY 649

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

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

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

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

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

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

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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

02 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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="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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

23 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

---



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 677

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°F/38°C) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2022 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JUL 2022 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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 <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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2022 23:59



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 705

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

---

28 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

01 AUG 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

---

04 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

08 AUG 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

15 AUG 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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="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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

---

<a href="#">Patient Cloud Open Date &amp; Time</a>	18 AUG 2022 00:01
--	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	22 AUG 2022 23:59
---	-------------------

---



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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 <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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

---

<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2022 00:01
--	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2022 23:59
---	-------------------

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 SEP 2022 23:59

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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="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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

15 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

---



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

22 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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 <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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

---

29 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

03 OCT 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

06 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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

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 ☐

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

13 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

---



US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

DAY 789

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°F/38°C) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

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

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

---

<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2022 00:01
--	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2022 23:59
---	-------------------

---

US3422101

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

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="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"/>

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2022 23:59

**US3422101**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 09 Jun 2021 17:32:16**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 17:15:48

US3422101

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:48:28

Generated On: 09 Jun 2021 17:32:16

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3422101

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:48:28

Generated On: 09 Jun 2021 17:32:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422101

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:07:24

Generated On: 09 Jun 2021 17:32:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3422101

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:07:24

Generated On: 09 Jun 2021 17:32:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422101

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:07:24

Generated On: 09 Jun 2021 17:32:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3422101

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:07:24

Generated On: 09 Jun 2021 17:32:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422101

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 23:07:24

Generated On: 09 Jun 2021 17:32:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3422101

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:07:24

Generated On: 09 Jun 2021 17:32:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422101

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:07:24

Generated On: 09 Jun 2021 17:32:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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

US3422101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 23:07:24

Generated On: 09 Jun 2021 17:32:16

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3422101

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:07:24

Generated On: 09 Jun 2021 17:32:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 MAR 2021

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



US3422101

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:07:24

Generated On: 09 Jun 2021 17:32:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 MAR 2021

Collection time (00:00-23:59)

09:40 (24 HR)

Collection date and time (derived)

25 MAR 2021 09:40

US3422101

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 23:07:24

Generated On: 09 Jun 2021 17:32:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3422101

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 15:34:09

Generated On: 09 Jun 2021 17:32:16

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*

US3422101

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:34:09

Generated On: 09 Jun 2021 17:32:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3422101**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3422101**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

Date of Contact	11 NOV 2020
Time of Contact	08:00
Date and Time of Contact (derived)	11 NOV 2020 08:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 NOV 2020	
Assessment Not Done	False	
O2 Saturation	099 %	
O2 Saturation Units	%	
Temperature	099.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

328 of 2667

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	11 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	099 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	098.9 F
-------------	---------

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

332 of 2667

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	12 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	098.1 F
-------------	---------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

336 of 2667

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	099 %	
O2 Saturation Units	%	
Temperature	098.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

340 of 2667

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	099 %	
O2 Saturation Units	%	
Temperature	098.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

344 of 2667

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	099 %	
O2 Saturation Units	%	
Temperature	099.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

348 of 2667

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	098 %	
O2 Saturation Units	%	
Temperature	098.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

352 of 2667

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

Date of Visit	12 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	12 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3422101

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 01 Apr 2021 23:07:24

Generated On: 09 Jun 2021 17:32:16

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	14 NOV 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3422101

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:07:24

Generated On: 09 Jun 2021 17:32:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3422101

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 23:07:24

Generated On: 09 Jun 2021 17:32:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 NOV 2020
Time of assessment (00:00-23:59)	08:00 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 08:00
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.1 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3422101

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 23:07:24

Generated On: 09 Jun 2021 17:32:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 NOV 2020

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



US3422101

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 01 Apr 2021 23:07:24

Generated On: 09 Jun 2021 17:32:16

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

12 NOV 2020

US3422101

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 23:07:24

Generated On: 09 Jun 2021 17:32:16

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

Visit date (dd MMM yyyy)	08 JAN 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
------------	---------------

US3422101

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 20:48:34

Generated On: 09 Jun 2021 17:32:16

Date of updated informed consent (*dd MMM yyyy*) 6 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 08 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3422101

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 23:07:24

Generated On: 09 Jun 2021 17:32:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	08 JAN 2021
Collection time ( <i>00:00-23:59</i> )	11:50 (24 HR)
Collection date and time (derived)	08 JAN 2021 11:50

US3422101

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 23:07:24

Generated On: 09 Jun 2021 17:32:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 JAN 2021
Collection time (00:00 - 23:59)	11:53
Collection Date and Time (derived)	08 JAN 2021 11:53

US3422101

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Mar 2021 21:30:04

Generated On: 09 Jun 2021 17:32:16

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3422101

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 15:34:07

Generated On: 09 Jun 2021 17:32:16

AEID

Adverse event

STREPTOCOCCAL  
PHARYNGITIS

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)

16 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 NOV 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 ☐

PRODUCTION RELEASE (v12.003

366 of 2667

EAB) (1725)

US3422101

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 15:34:07

Generated On: 09 Jun 2021 17:32:16

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with <input type="radio"/>
	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)	



US3422101

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 15:34:07

Generated On: 09 Jun 2021 17:32:16

AEID	USA-US082-2021-MRNA-1273-P30 1000006
Adverse event	ILEUS
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)	13 FEB 2021
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)	15 FEB 2021
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 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)	13 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	15 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

368 of 2667

US3422101

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 15:34:07

Generated On: 09 Jun 2021 17:32:16

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

US3422101

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 15:34:07

Generated On: 09 Jun 2021 17:32:16

---

SUBJECT PRESENTED TO THE  
ED ON 13FEB2021 FOR ILEUS,  
STATUS POST SCHEDULED  
OUTPATIENT PROCEDURE FOR  
PILONIDAL CYST EXCISION ON  
12FEB2021. POST -PROCEDURE  
SUBJECT TOOK OXYCODONE  
FOR PAIN MANAGEMENT,  
ILEUS RELATED TO POST-OP  
PAIN MANAGEMENT. STUDY  
SITE NOTIFIED OF SURGERY  
AND HOSPITALIZATION ON  
19FEB2021

---

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

---

US3422101

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 15:34:07

Generated On: 09 Jun 2021 17:32:16

AEID	
Adverse event	WORSENING BIPOLAR DISORDER II
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)	15 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
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"/>

US3422101

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 15:34:07

Generated On: 09 Jun 2021 17:32:16

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 type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with <input type="radio"/>
	Sequelae <input type="radio"/>
	Recovering/Resolving <input checked="" 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)	

US3422101

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 15:34:07

Generated On: 09 Jun 2021 17:32:16

AEID	
Adverse event	STREPTOCOCCAL PHARYNGITIS
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)	15 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
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"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

373 of 2667

US3422101

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 15:34:07

Generated On: 09 Jun 2021 17:32:16

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with <input type="radio"/>
	Sequelae <input type="radio"/>
	Recovering/Resolving <input checked="" 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)	

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 01 Apr 2021 23:07:23

Generated On: 09 Jun 2021 17:32:16

---

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

Yes ☒

No ☐

---

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

---



US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication PREGABLIN

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

376 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication LAMOTRIGINE

Prophylaxis Yes ☐  
No ☒

Indication BIPOLAR DISORDER II

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

378 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2011	
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"/>

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication TOPIRAMATE

Prophylaxis Yes ☐  
No ☒

Indication OBSESSIVE COMPULSIVE  
DISORDER

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

380 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	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	UNK 2018
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"/>

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication PROPRANOLOL

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 120

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

382 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
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"/>



US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication TRAZADONE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

384 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication LORAZEPAM

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

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 ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

386 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2011	
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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication SUMATRIPTAIN

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINES

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

388 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	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)		23 JAN 2020
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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED MYALGIAS/PAIN  
AT INJECTION SITE

Dose per administration 1000

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)

390 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	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)		22 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)		24 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"/>



US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

392 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		12 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐  
No ☒

Indication STREPTOCOCCAL  
PHARYNGITIS

Dose per administration 875

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)

394 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	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)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 NOV 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"/>

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication LORATADINE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

396 of 2667

EAB) (1725)

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1990	
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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication KETAMINE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING BIPOLAR  
DISORDER II

Dose per administration 80

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)

398 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	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)		11 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
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 checked="" type="checkbox"/>
	804	<input type="checkbox"/>



US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication LITHIUM

Prophylaxis Yes ☐  
No ☒

Indication WORSENING BIPOLAR  
DISORDER II

Dose per administration 300

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)

400 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN DEC 2020	
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"/>

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication OXYCODONE

Prophylaxis Yes ☐  
No ☒

Indication EXCISION OF PILONIDAL CYST

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

402 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	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)		12 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 16 FEB 2021		
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"/>

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication BISACODYL

Prophylaxis Yes ☐  
No ☒

Indication ILEUS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

404 of 2667

EAB) (1725)

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input checked="" type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		14 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication KETOROLAC

Prophylaxis Yes ☐  
No ☒

Indication ILEUS

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

406 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	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)		14 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 FEB 2021
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"/>



US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication LACTULOSE

Prophylaxis Yes ☐  
No ☒

Indication ILEUS

Dose per administration 20

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

408 of 2667

EAB) (1725)

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	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)		15 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 15 FEB 2021		
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"/>

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication MAGNESIUM CITRATE

Prophylaxis Yes ☐  
No ☒

Indication ILEUS

Dose per administration 296

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

410 of 2667

EAB) (1725)

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	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)		14 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 FEB 2021
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"/>

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication MAGNESIUM HYDROXIDE

Prophylaxis Yes ☐  
No ☒

Indication ILEUS

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

412 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 14 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐  
No ☒

Indication ILEUS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

414 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)		14 FEB 2021
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐  
No ☒

Indication ILEUS

Dose per administration 750

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

416 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	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)		14 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 FEB 2021
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"/>

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication ONDASETRON

Prophylaxis Yes ☐  
No ☒

Indication ILEUS

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 ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

418 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		14 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication MIRALAX

Prophylaxis Yes ☐  
No ☒

Indication ILEUS

Dose per administration 17

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

420 of 2667

EAB) (1725)

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	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)		14 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 FEB 2021
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"/>

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication SENNOSIDE-DOCUSATE

Prophylaxis Yes ☐  
No ☒

Indication ILEUS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

422 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	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)		13 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 FEB 2021
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"/>



US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication HALDOL

Prophylaxis Yes ☐  
No ☒

Indication ILEUS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

424 of 2667

EAB) (1725)

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	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)		14 FEB 2021
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 15 FEB 2021		
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"/>	

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐  
No ☒

Indication STREPTOCOCCAL  
PHARYNGITIS

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

426 of 2667

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 15:34:08

Generated On: 09 Jun 2021 17:32:16

	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)		15 APR 2021
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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3422101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 20:48:34

Generated On: 09 Jun 2021 17:32:16

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3422101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 20:48:34

Generated On: 09 Jun 2021 17:32:16

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
12 FEB 2021	EXCISION OF PILONIDAL CYST	Medical History	

US3422101

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:32:16

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

US3422101

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:32:16

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 ☐



US3422101

Folder: SAE USA-US082-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 08 Apr 2021 14:05:27

Generated On: 09 Jun 2021 17:32:16

SAEID	USA-US082-2021-MRNA-1273-P301000006
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	CLARENCE
Investigator's Last Name	CREECH
Site Address: Street	CCC-5311 MCN
Site Address: City	NASHVILLE
Site Address: State	TN
Site Address: Postal Code	37027
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3422101

Folder: SAE USA-US082-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Apr 2021 14:05:27

Generated On: 09 Jun 2021 17:32:16

SAEID	USA-US082-2021-MRNA-1273-P301000006
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	CLARENCE
Investigator's Last Name	CREECH
Site Address: Street	CCC-5311 MCN
Site Address: City	NASHVILLE
Site Address: State	TN
Site Address: Postal Code	37027
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/FEB/2021 12:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3422101

Folder: SAE USA-US082-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Apr 2021 14:05:27

Generated On: 09 Jun 2021 17:32:16

SAEID	USA-US082-2021-MRNA-1273-P301000006
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	CLARENCE
Investigator's Last Name	CREECH
Site Address: Street	CCC-5311 MCN
Site Address: City	NASHVILLE
Site Address: State	TN
Site Address: Postal Code	37027
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/MAR/2021 09:51
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

US3422101

Folder: SAE USA-US082-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 08 Apr 2021 14:05:27

Generated On: 09 Jun 2021 17:32:16

SAEID	USA-US082-2021-MRNA-1273-P301000006
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	CLARENCE
Investigator's Last Name	CREECH
Site Address: Street	CCC-5311 MCN
Site Address: City	NASHVILLE
Site Address: State	TN
Site Address: Postal Code	37027
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/MAR/2021 06:34
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

US3422101

Folder: SAE USA-US082-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 08 Apr 2021 14:05:27

Generated On: 09 Jun 2021 17:32:16

SAEID	USA-US082-2021-MRNA-1273-P301000006
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	CLARENCE
Investigator's Last Name	CREECH
Site Address: Street	CCC-5311 MCN
Site Address: City	NASHVILLE
Site Address: State	TN
Site Address: Postal Code	37027
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/APR/2021 13:34
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

US3422101 (Prod: Vanderbilt University Medical Center)

**US3422101**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:32:16**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'US3422101'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:19:33

US3422101

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:32:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4) Naomi Kown (b) (4)	25 Aug 2020 14:31:22



**US3422101**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '25 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:19:34

**US3422101**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Clinic (Clinic)'	(b) (4) Naomi Kown (b) (4) (b) (4)	25 Aug 2020 14:31:22

**US3422101**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered 'SCRN'	System	25 Aug 2020 14:31:22

**US3422101**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered (b) (6) 1985'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:19:35

**US3422101**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:32:16**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '35'	(b) (4) Naomi Kown (b) (4) (b) (4)	25 Aug 2020 14:31:48

**US3422101**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:32:16**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered 'YEARS'	System	25 Aug 2020 14:31:48

**US3422101**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:32:16**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered '35'	System	25 Aug 2020 14:32:21

**US3422101**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:32:16**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Male (M)'	(b) (4) Naomi Kown (b) (4)	25 Aug 2020 14:31:48



US3422101

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:32:16

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Naomi Kown (b) (4)	25 Aug 2020 14:31:48

**US3422101**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:32:16**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'I'	(b) (4) Naomi Kown (b) (4)	25 Aug 2020 14:31:48
	(b) (4)	

**US3422101**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:32:16**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) Naomi Kown (b) (4)	25 Aug 2020 14:31:48
	(b) (4)	

**US3422101**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:32:16**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) Naomi Kown (b) (4) (b) (4)	25 Aug 2020 14:31:48

**US3422101**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:32:16**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) Naomi Kown (b) (4)	25 Aug 2020 14:31:48

**US3422101**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:32:16**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) Naomi Kown (b) (4)	25 Aug 2020 14:31:48

**US3422101**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:32:16**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) Naomi Kown (b) (4) (b) (4)	25 Aug 2020 14:31:48

**US3422101**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:32:16**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4) Naomi Kown (b) (4) (b) (4)	25 Aug 2020 14:31:48



**US3422101**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:32:16**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) Naomi Kown (b) (4) (b) (4)	25 Aug 2020 14:31:48

**US3422101**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:32:16**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) Naomi Kown (b) (4)	25 Aug 2020 14:31:48

**US3422101**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '25 Aug 2020'	(b) (4) Naomi Kown (b) (4)	25 Aug 2020 14:32:21
	(b) (4)	

**US3422101**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered 'Aug 2020'	System	25 Aug 2020 14:32:21

**US3422101**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered '2020'	System	25 Aug 2020 14:32:21

**US3422101**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:32:16**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Amendment 3 (3)'	(b) (4) Naomi Kown (b) (4) (b) (4)	25 Aug 2020 14:32:21

**US3422101**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4) Naomi Kown (b) (4)	25 Aug 2020 14:32:21

**US3422101**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4) Naomi Kown (b) (4)	25 Aug 2020 14:32:21



**US3422101**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:32:16**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4) Naomi Kown (b) (4)	25 Aug 2020 14:32:21
	(b) (4)	

**US3422101**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:32:16**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	(b) (4) Naomi Kown (b) (4)	25 Aug 2020 14:32:21

**US3422101**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:32:16**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:19:34

**US3422101**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:32:16**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered 'I'	System	25 Aug 2020 14:32:35

**US3422101**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4) Naomi Kown (b) (4)	25 Aug 2020 14:32:35

**US3422101**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 17:32:16**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4) Cindy Trimmer (b) (4)	25 Aug 2020 17:17:20

US3422101

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:32:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 17:18:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 17:18:49
Data point term sent to Coder	System	25 Aug 2020 17:17:54
User entered 'Anxiety'	Cindy Trimmer (b) (4)	25 Aug 2020 17:17:45
	(b) (4)	

**US3422101**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'UN UNK 2011' reason for change:	(b) (4)	
Data Entry Error	Cindy Trimmer (b) (4)	16 Oct 2020 18:10:23
User entered '30 Jun 2011'	(b) (4)	
	Cindy Trimmer (b) (4)	25 Aug 2020 17:17:45
	(b) (4)	



**US3422101**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	25 Aug 2020 17:17:45

**US3422101**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4) Cindy Trimmer (b) (4)	25 Aug 2020 17:17:45

**US3422101**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	25 Aug 2020 17:17:45

**US3422101**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	25 Aug 2020 17:17:45

**US3422101**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered 'Jan 2011'	System	16 Oct 2020 18:10:23
User entered 'Jun 2011'	System	25 Aug 2020 17:17:45

**US3422101**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered '2011'	System	25 Aug 2020 17:17:45

**US3422101**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered empty.	System	25 Aug 2020 17:17:45

**US3422101**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered empty.	System	25 Aug 2020 17:17:45



US3422101

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:32:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Obsessive-compulsive disorders and symptoms, PT: Obsessive-compulsive disorder, LLT: Obsessive-compulsive disorder - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	25 Aug 2020 17:19:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 17:19:37
Data point term sent to Coder	System	25 Aug 2020 17:18:55
User entered 'Obsessive Compulsive Disorder'	Cindy Trimmer (b) (4) (b) (4)	25 Aug 2020 17:18:11

**US3422101**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'UN UNK 2018' reason for change:	(b) (4)	
Data Entry Error	Cindy Trimmer (b) (4)	16 Oct 2020 18:10:30
User entered '30 Jun 2018'	(b) (4)	
	Cindy Trimmer (b) (4)	25 Aug 2020 17:18:11
	(b) (4)	

**US3422101**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	25 Aug 2020 17:18:11

**US3422101**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:18:11

**US3422101**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	25 Aug 2020 17:18:11

**US3422101**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	25 Aug 2020 17:18:11

**US3422101**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered 'Jan 2018'	System	16 Oct 2020 18:10:30
User entered 'Jun 2018'	System	25 Aug 2020 17:18:11

**US3422101**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered '2018'	System	25 Aug 2020 17:18:11



**US3422101**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered empty.	System	25 Aug 2020 17:18:11

**US3422101**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered empty.	System	25 Aug 2020 17:18:11

US3422101

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:32:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar II disorder, LLT: Bipolar II disorder - version MedDRA\23.0.	Coder Import (b) (4)	25 Aug 2020 20:55:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	25 Aug 2020 20:55:40
Data point term sent to Coder	System	25 Aug 2020 17:18:57
User entered 'Bipolar Disorder II'	Cindy Trimmer (b) (4)	25 Aug 2020 17:18:41
	(b) (4)	

**US3422101**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'UN UNK 2011' reason for change:	(b) (4)	
Data Entry Error	Cindy Trimmer (b) (4)	16 Oct 2020 18:10:36
User entered '30 Jun 2011'	(b) (4)	
	Cindy Trimmer (b) (4)	25 Aug 2020 17:18:41
	(b) (4)	

**US3422101**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	25 Aug 2020 17:18:41

**US3422101**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4) Cindy Trimmer (b) (4)	25 Aug 2020 17:18:41

**US3422101**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	25 Aug 2020 17:18:41

**US3422101**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	25 Aug 2020 17:18:41



**US3422101**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered 'Jan 2011'	System	16 Oct 2020 18:10:36
User entered 'Jun 2011'	System	25 Aug 2020 17:18:41

**US3422101**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered '2011'	System	25 Aug 2020 17:18:41

**US3422101**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered empty.	System	25 Aug 2020 17:18:41

**US3422101**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered empty.	System	25 Aug 2020 17:18:41

US3422101

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:32:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	25 Aug 2020 17:20:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 17:20:30
Data point term sent to Coder	System	25 Aug 2020 17:19:58
User entered 'Migraines'	Cindy Trimmer (b) (4) (b) (4)	25 Aug 2020 17:18:57

**US3422101**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'UN UNK 2017' reason for change:	(b) (4)	
Data Entry Error	Cindy Trimmer (b) (4)	16 Oct 2020 18:10:43
User entered '30 Jun 2017'	(b) (4)	
	Cindy Trimmer (b) (4)	25 Aug 2020 17:18:57
	(b) (4)	

**US3422101**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) Cindy Trimmer (b) (4)	25 Aug 2020 17:18:57

**US3422101**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:18:57



**US3422101**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	25 Aug 2020 17:18:57
	(b) (4)	

**US3422101**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	25 Aug 2020 17:18:57

**US3422101**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered 'Jan 2017'	System	16 Oct 2020 18:10:43
User entered 'Jun 2017'	System	25 Aug 2020 17:18:57

**US3422101**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered '2017'	System	25 Aug 2020 17:18:57

**US3422101**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered empty.	System	25 Aug 2020 17:18:57

**US3422101**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered empty.	System	25 Aug 2020 17:18:57

US3422101

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:32:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 18:48:28
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Skin structures and soft tissue infections, PT: Pilonidal cyst, LLT: Pilonidal cyst - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	22 Feb 2021 19:32:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 19:32:01
Data point term sent to Coder	System	22 Feb 2021 19:30:56
User entered 'Pilonidal cyst'	(b) (4), (b) (6)	22 Feb 2021 19:30:08

**US3422101**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 18:48:28
User entered 'un Dec 2019'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:30:08



**US3422101**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 18:48:28
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:30:08

**US3422101**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 18:48:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:30:08

**US3422101**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 18:48:28
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:30:08

**US3422101**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 18:48:28
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 19:30:08

**US3422101**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered 'Dec 2019'	System	22 Feb 2021 19:30:08

**US3422101**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered '2019'	System	22 Feb 2021 19:30:08

**US3422101**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered empty.	System	22 Feb 2021 19:30:08

**US3422101**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered empty.	System	22 Feb 2021 19:30:08



US3422101

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:32:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:40:49
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	08 Mar 2021 19:34:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Mar 2021 19:34:42
Data point term sent to Coder	System	08 Mar 2021 19:19:02
User entered 'Seasonal Allergies'	(b) (4), (b) (6)	08 Mar 2021 19:18:18

**US3422101**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:40:49
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 19:18:18

**US3422101**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:40:49
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 19:18:18

**US3422101**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:40:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 19:18:18

**US3422101**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:40:49
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 19:18:18

**US3422101**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	18 Mar 2021 21:40:49
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 19:18:18

**US3422101**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered 'Jan 1990'	System	08 Mar 2021 19:18:18

**US3422101**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered '1990'	System	08 Mar 2021 19:18:18



**US3422101**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered empty.	System	08 Mar 2021 19:18:18

**US3422101**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered empty.	System	08 Mar 2021 19:18:18

US3422101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4) Cindy Trimmer (b) (4)	25 Aug 2020 17:19:37

**US3422101**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '25 Aug 2020'	(b) (4) Cindy Trimmer (b) (4)	25 Aug 2020 17:19:37
	(b) (4)	

**US3422101**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '09:21'	(b) (4) Cindy Trimmer (b) (4)	25 Aug 2020 17:19:37

**US3422101**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered '25 Aug 2020 09:21'	System	25 Aug 2020 17:19:37

US3422101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '70' in	(b) (4) Cindy Trimmer (b) (4)	25 Aug 2020 17:19:37
DataPoint set to visible.	(b) (4) System	25 Aug 2020 14:32:35

US3422101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '165' lb	(b) (4) Cindy Trimmer (b) (4)	25 Aug 2020 17:19:37
DataPoint set to visible.	(b) (4) System	25 Aug 2020 14:32:35



US3422101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
Amendment Manager: User entered '23.72454'	System	17 Sep 2020 00:22:32
User entered '23.7'	System	25 Aug 2020 17:19:37
DataPoint set to visible.	System	25 Aug 2020 14:32:35

**US3422101**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered 'kg/m2'	System	25 Aug 2020 17:19:37
DataPoint set to visible.	System	25 Aug 2020 14:32:35

US3422101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User closed query 'Per CDM: Thank you for your response. However, ND should be recorded within the CRF data field for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP. Please update these fields. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 12:48:06
Query 'Per CDM: Thank you for your response. However, ND should be recorded within the CRF data field for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP. Please update these fields. ' answered with 'corrected' (Site from DM).	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:06:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	25 Sep 2020 14:06:26
User opened query 'Per CDM: Thank you for your response. However, ND should be recorded within the CRF data field for Temperature, Pulse, Respiratory Rate, Systolic BP and Diastolic BP. Please update these fields. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:01:48
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:01:48
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 14:01:33
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 20:20:18
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly' answered with 'ND' (Site from DM).	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 20:20:14
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:20:10
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4) (b) (4)	21 Sep 2020 20:20:10

US3422101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

Temperature (xxx.x)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 14:30:19
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Aug 2020 17:19:50
User entered '98.7' F reason for change: Data Entry Error	Cindy Trimmer (b) (4)	25 Aug 2020 17:19:50
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Aug 2020 17:19:37
User entered '98.7' (non-conformant).	Cindy Trimmer (b) (4)	25 Aug 2020 17:19:37

**US3422101**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty; reason for change Data Entry Error	(b) (4)	
	Cindy Trimmer (b) (4)	21 Sep 2020 20:20:10
User entered 'Oral (Oral)'	(b) (4)	
	Cindy Trimmer (b) (4)	25 Aug 2020 17:19:37
	(b) (4)	

**US3422101**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	25 Aug 2020 17:19:37
	(b) (4)	

US3422101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 14:06:26
User closed query 'Data is required. Please provide.' (Site from System).	Cindy Trimmer (b) (4)	25 Sep 2020 14:01:34
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 20:20:21
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:20:10
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4)	21 Sep 2020 20:20:10
User entered '61'	(b) (4)	25 Aug 2020 17:19:37

**US3422101**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered 'bpm'	System	25 Sep 2020 14:06:26
User entered empty.	System	21 Sep 2020 20:20:10
User entered 'bpm'	System	25 Aug 2020 17:19:37



US3422101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4)	25 Sep 2020 14:06:26
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	25 Sep 2020 14:01:36
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 14:01:36
User opened query 'Data is required. Please provide.' (Site from System).	Cindy Trimmer (b) (4)	21 Sep 2020 20:20:23
User entered empty; reason for change Data Entry Error	(b) (4)	21 Sep 2020 20:20:10
User entered '16'	System	21 Sep 2020 20:20:10
	Cindy Trimmer (b) (4)	21 Sep 2020 20:20:10
	(b) (4)	21 Sep 2020 20:20:10
	Cindy Trimmer (b) (4)	25 Aug 2020 17:19:37
	(b) (4)	25 Aug 2020 17:19:37

US3422101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered 'breaths/min'	System	25 Sep 2020 14:06:26
User entered empty.	System	21 Sep 2020 20:20:10
User entered 'breaths/min'	System	25 Aug 2020 17:19:37

US3422101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 14:06:26
User closed query 'Data is required. Please provide.' (Site from System).	Cindy Trimmer (b) (4)	25 Sep 2020 14:01:37
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 20:20:26
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:20:10
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4)	21 Sep 2020 20:20:10
User entered '111'	(b) (4)	25 Aug 2020 17:19:37

**US3422101**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered 'mmHg'	System	25 Sep 2020 14:06:26
User entered empty.	System	21 Sep 2020 20:20:10
User entered 'mmHg'	System	25 Aug 2020 17:19:37

US3422101

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 14:06:26
User closed query 'Data is required. Please provide.' (Site from System).	Cindy Trimmer (b) (4)	25 Sep 2020 14:01:44
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 20:20:30
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 20:20:10
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4)	21 Sep 2020 20:20:10
User entered '82'	(b) (4)	25 Aug 2020 17:19:37

**US3422101**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered 'mmHg'	System	25 Sep 2020 14:06:26
User entered empty.	System	21 Sep 2020 20:20:10
User entered 'mmHg'	System	25 Aug 2020 17:19:37

**US3422101**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18

**US3422101**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18



**US3422101**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:32:16**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4) Cindy Trimmer (b) (4)	25 Aug 2020 17:20:04

**US3422101**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:32:16**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '25 Aug 2020'	Cindy Trimmer (b) (4)	25 Aug 2020 17:20:04

US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21

US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21

US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21

US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21

US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21

US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21



US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21

US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21

US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21

US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21

US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21

US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21

US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21

US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21



US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21

US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21

US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21

US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21

US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21

US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21

US3422101

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:21

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	Naomi Kown (b) (4)	25 Aug 2020 14:32:55



**US3422101**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '25 Aug 2020'	Naomi Kown (b) (4)	25 Aug 2020 14:32:55

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Clinic (Clinic)'	Naomi Kown (b) (4)	25 Aug 2020 14:32:55

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'VISIT1'	System	25 Aug 2020 14:32:55

US3422101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '25 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:29:56

US3422101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '108078'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:29:56

US3422101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:29:56

US3422101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:35

US3422101

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:35



**US3422101**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:35

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:35

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:32:16**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 14:41:35

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	Cindy Trimmer (b) (4)	21 Sep 2020 20:20:34
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 02:49:43
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:49:42

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:32:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 09:23:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4)	25 Sep 2020 14:06:50
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' answered with 'ND' (Site from DM).	Cindy Trimmer (b) (4)	21 Sep 2020 20:20:46
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4)	21 Sep 2020 20:20:43
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 18:36:09
User entered '70' in	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:32:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 14:06:50
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4)	21 Sep 2020 20:20:43
User entered '165' lb	(b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:32:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 09:23:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4)	25 Sep 2020 14:06:50
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' answered with 'ND' (Site from DM).	Cindy Trimmer (b) (4)	21 Sep 2020 20:20:46
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4)	21 Sep 2020 20:20:43
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 18:36:09
User entered '70' in	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:32:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4)	25 Sep 2020 14:06:50
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4)	21 Sep 2020 20:20:43
User entered '165' lb	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09



US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User accepted default value 'Pre-Dose (PREDOSE)'	Cindy Trimmer (b) (4) (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '25 Aug 2020'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '09:21'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered '25 Aug 2020 09:21'	System	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '98.7' F	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Oral (Oral)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09



US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '61'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'bpm'	System	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '16'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'breaths/min'	System	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '111'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'mmHg'	System	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '82'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'mmHg'	System	25 Aug 2020 17:21:09



US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:32:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 09:23:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4)	25 Sep 2020 14:06:50
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' answered with 'ND' (Site from DM).	Cindy Trimmer (b) (4)	21 Sep 2020 20:20:46
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4)	21 Sep 2020 20:20:43
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 18:36:09
User entered '70' in	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:32:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered missing code ND - Not Done; reason for change Data Entry Error	Cindy Trimmer (b) (4)	25 Sep 2020 14:06:50
User entered empty; reason for change Data Entry Error	Cindy Trimmer (b) (4)	21 Sep 2020 20:20:43
User entered '165' lb	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User accepted default value 'Post-Dose (POSTDOSE)'	Cindy Trimmer (b) (4) (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '25 Aug 2020'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '10:22'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered '25 Aug 2020 10:22'	System	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '97.7' F	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09



US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Oral (Oral)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '55'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'bpm'	System	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '18'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'breaths/min'	System	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '102'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

US3422101

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'mmHg'	System	25 Aug 2020 17:21:09



**US3422101**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '64'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:09

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'mmHg'	System	25 Aug 2020 17:21:09

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:32:16**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:23

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:32:16**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '25 Aug 2020'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:23

US3422101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:32:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	Naomi Kown (b) (4)	25 Aug 2020 14:55:14

US3422101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:32:16

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4) Naomi Kown (b) (4)	25 Aug 2020 14:55:14

US3422101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	Naomi Kown (b) (4)	25 Aug 2020 14:55:14

US3422101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:32:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 14:55:14



US3422101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:32:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '25 Aug 2020'	Naomi Kown (b) (4)	25 Aug 2020 14:55:14

US3422101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '09:52'	Naomi Kown (b) (4)	25 Aug 2020 14:55:14

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered '25 Aug 2020 09:52'	System	25 Aug 2020 14:55:14

US3422101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Left Arm (LEFT ARM)'	Naomi Kown (b) (4)	25 Aug 2020 14:55:14

US3422101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:32:16

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'ONCE'	System	25 Aug 2020 14:55:14

US3422101

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:32:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 14:55:14

US3422101

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:47

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:32:16**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '25 Aug 2020'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:47



**US3422101**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:32:16**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '09:25'	Cindy Trimmer (b) (4)	25 Aug 2020 17:21:47

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered '25 Aug 2020 09:25'	System	25 Aug 2020 17:21:47

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 17:32:16**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '25 Aug 2020'	Cindy Trimmer (b) (4)	25 Aug 2020 17:22:02

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:22:02

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:22:02

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '09:23'	Cindy Trimmer (b) (4)	25 Aug 2020 17:22:02

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered '25 Aug 2020 09:23'	System	25 Aug 2020 17:22:02

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:22:02



**US3422101**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:22:02

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:22:02

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered empty.	System	25 Aug 2020 17:22:02

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	25 Aug 2020 18:27:54

**US3422101**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'I'	System	25 Aug 2020 18:27:54

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T10:26:04', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'e89a4c0e-5162-4b71-af6a-3e7af6c470bf' User entered 'Yes (Y)'	System	25 Aug 2020 15:26:20
	System	25 Aug 2020 15:26:20

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T10:26:09', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'e89a4c0e-5162-4b71-af6a-3e7af6c470bf' User entered '97.7'	System	25 Aug 2020 15:26:20
	System	25 Aug 2020 15:26:20



US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T10:26:13', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'e89a4c0e-5162-4b71-af6a-3e7af6c470bf' User entered 'No (N)'	System	25 Aug 2020 15:26:20
	System	25 Aug 2020 15:26:20

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T10:26:16', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'e89a4c0e-5162-4b71-af6a-3e7af6c470bf' User entered '25 Aug 2020 10:26'	System	25 Aug 2020 15:26:20
	System	25 Aug 2020 15:26:20

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '25 Aug 2020 10:12'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '25 Aug 2020 12:42'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T14:37:06', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '020dbc94-e062-4861-a42d-4200a5268f65' User entered 'Yes (Y)'	System	25 Aug 2020 19:37:26
	System	25 Aug 2020 19:37:26

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T14:37:19', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '020dbc94-e062-4861-a42d-4200a5268f65' User entered '96.9'	System	25 Aug 2020 19:37:26
	System	25 Aug 2020 19:37:26

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T14:37:21', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '020dbc94-e062-4861-a42d-4200a5268f65'	System	25 Aug 2020 19:37:26
User entered 'No (N)'	System	25 Aug 2020 19:37:26



**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T14:37:24', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '020dbc94-e062-4861-a42d-4200a5268f65' User entered '25 Aug 2020 14:37'	System	25 Aug 2020 19:37:26
	System	25 Aug 2020 19:37:26

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '25 Aug 2020 13:37'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 2'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:32:16

Was **TEMPERATURE** taken?

(b)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-26T17:13:34', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '1477b7ed-ab14-4e6a-bc0a-b1267226c54e' User entered 'Yes (Y)'	System	26 Aug 2020 22:13:45
	System	26 Aug 2020 22:13:45

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:32:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-26T17:13:38', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '1477b7ed-ab14-4e6a-bc0a-b1267226c54e' User entered '97.8'	System	26 Aug 2020 22:13:45
	System	26 Aug 2020 22:13:45

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-26T17:13:40', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '1477b7ed-ab14-4e6a-bc0a-b1267226c54e' User entered 'No (N)'	System	26 Aug 2020 22:13:45
	System	26 Aug 2020 22:13:45

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:32:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-26T17:13:42', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '1477b7ed-ab14-4e6a-bc0a-b1267226c54e' User entered '26 Aug 2020 17:13'	System	26 Aug 2020 22:13:45
	System	26 Aug 2020 22:13:45



US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:32:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:32:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 3'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:32:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-27T12:45:23', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'bd76c6ac-72c5-427f-9945-b3ddc1d742d1' User entered 'Yes (Y)'	System	27 Aug 2020 17:45:45
	System	27 Aug 2020 17:45:45

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:32:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-27T12:45:31', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'bd76c6ac-72c5-427f-9945-b3ddc1d742d1' User entered '97.2'	System	27 Aug 2020 17:45:45
	System	27 Aug 2020 17:45:45

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-27T12:45:36', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'bd76c6ac-72c5-427f-9945-b3ddc1d742d1' User entered 'No (N)'	System	27 Aug 2020 17:45:45
	System	27 Aug 2020 17:45:45

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-27T12:45:43', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'bd76c6ac-72c5-427f-9945-b3ddc1d742d1' User entered '27 Aug 2020 12:45'	System	27 Aug 2020 17:45:45
	System	27 Aug 2020 17:45:45

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:32:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 14:55:14



**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 4'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:32:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-28T12:46:51', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '52fd01fc-eb7c-4888-87fd-df790441e14b' User entered 'Yes (Y)'	System	28 Aug 2020 17:47:00
	System	28 Aug 2020 17:47:00

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:32:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-28T12:46:54', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '52fd01fc-eb7c-4888-87fd-df790441e14b' User entered '97.7'	System	28 Aug 2020 17:47:00
	System	28 Aug 2020 17:47:00

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-28T12:46:56', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '52fd01fc-eb7c-4888-87fd-df790441e14b'	System	28 Aug 2020 17:47:00
User entered 'No (N)'	System	28 Aug 2020 17:47:00

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-28T12:46:58', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '52fd01fc-eb7c-4888-87fd-df790441e14b' User entered '28 Aug 2020 12:46'	System	28 Aug 2020 17:47:00
	System	28 Aug 2020 17:47:00

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:32:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 14:55:14



US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 5'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:32:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-30T09:07:01', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '8b89f65c-1f70-45cf-9cd9-766dce3d95f7' User entered 'Yes (Y)'	System	30 Aug 2020 14:07:16
	System	30 Aug 2020 14:07:16

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:32:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-30T09:07:06', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '8b89f65c-1f70-45cf-9cd9-766dce3d95f7' User entered '98.2'	System	30 Aug 2020 14:07:16
	System	30 Aug 2020 14:07:16

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-30T09:07:09', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '8b89f65c-1f70-45cf-9cd9-766dce3d95f7'	System	30 Aug 2020 14:07:16
User entered 'No (N)'	System	30 Aug 2020 14:07:16

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-30T09:07:11', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '8b89f65c-1f70-45cf-9cd9-766dce3d95f7' User entered '30 Aug 2020 09:07'	System	30 Aug 2020 14:07:16
	System	30 Aug 2020 14:07:16

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:32:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 6'	System	25 Aug 2020 14:55:14



US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:32:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-31T09:40:44', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '122328ea-3214-4086-b2e4-5d23be67b4bc' User entered 'Yes (Y)'	System	31 Aug 2020 14:40:56
	System	31 Aug 2020 14:40:56

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:32:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-31T09:40:49', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '122328ea-3214-4086-b2e4-5d23be67b4bc' User entered '98.2'	System	31 Aug 2020 14:40:56
	System	31 Aug 2020 14:40:56

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-31T09:40:53', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '122328ea-3214-4086-b2e4-5d23be67b4bc'	System	31 Aug 2020 14:40:56
User entered 'No (N)'	System	31 Aug 2020 14:40:56

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:32:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-31T09:40:55', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '122328ea-3214-4086-b2e4-5d23be67b4bc' User entered '31 Aug 2020 09:40'	System	31 Aug 2020 14:40:56
	System	31 Aug 2020 14:40:56

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:32:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 7'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-01T09:26:48', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'acb6c7b7-55b7-4e2f-9b3e-87e6d4e2d4fc' User entered 'Yes (Y)'	System	01 Sep 2020 14:27:01
	System	01 Sep 2020 14:27:01



US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:32:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-01T09:26:53', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'acb6c7b7-55b7-4e2f-9b3e-87e6d4e2d4fc' User entered '98.8'	System	01 Sep 2020 14:27:01
	System	01 Sep 2020 14:27:01

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-01T09:26:56', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'acb6c7b7-55b7-4e2f-9b3e-87e6d4e2d4fc'	System	01 Sep 2020 14:27:01
User entered 'No (N)'	System	01 Sep 2020 14:27:01

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-01T09:26:57', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'acb6c7b7-55b7-4e2f-9b3e-87e6d4e2d4fc' User entered '01 Sep 2020 09:26'	System	01 Sep 2020 14:27:01
	System	01 Sep 2020 14:27:01

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:32:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:32:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T10:26:51', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '05293529-66ed-4c3b-acac-c676346bb4c2' User entered 'None (1)'	System	25 Aug 2020 15:27:25
	System	25 Aug 2020 15:27:25

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T10:26:59', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '05293529-66ed-4c3b-acac-c676346bb4c2'	System	25 Aug 2020 15:27:25
User entered 'No (N)'	System	25 Aug 2020 15:27:25



US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T10:27:04', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '05293529-66ed-4c3b-acac-c676346bb4c2' User entered 'No (N)'	System	25 Aug 2020 15:27:25
	System	25 Aug 2020 15:27:25

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T10:27:19', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '05293529-66ed-4c3b-acac-c676346bb4c2' User entered 'None (1)'	System	25 Aug 2020 15:27:25
	System	25 Aug 2020 15:27:25

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T10:27:22', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '05293529-66ed-4c3b-acac-c676346bb4c2' User entered '25 Aug 2020 10:27'	System	25 Aug 2020 15:27:25
	System	25 Aug 2020 15:27:25

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '25 Aug 2020 10:12'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '25 Aug 2020 12:42'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T14:37:33', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '97de7fb0-59b3-4881-b688-60939c95fff2'	System	25 Aug 2020 19:40:24
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 19:40:24

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T14:37:52', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '97de7fb0-59b3-4881-b688-60939c95fff2'	System	25 Aug 2020 19:40:24
User entered 'No (N)'	System	25 Aug 2020 19:40:24



US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T14:40:06', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '97de7fb0-59b3-4881-b688-60939c95fff2'	System	25 Aug 2020 19:40:24
User entered 'No (N)'	System	25 Aug 2020 19:40:24

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T14:40:18', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '97de7fb0-59b3-4881-b688-60939c95fff2'	System	25 Aug 2020 19:40:24
User entered 'None (1)'	System	25 Aug 2020 19:40:24

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T14:40:20', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '97de7fb0-59b3-4881-b688-60939c95fff2'	System	25 Aug 2020 19:40:24
User entered '25 Aug 2020 14:40'	System	25 Aug 2020 19:40:24

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '25 Aug 2020 13:37'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 2'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-26T17:14:53', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '596524d0-6831-4c69-adb6-89b7e1395046'	System	26 Aug 2020 22:15:48
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	26 Aug 2020 22:15:48

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:32:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-26T17:15:02', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '596524d0-6831-4c69-adb6-89b7e1395046'	System	26 Aug 2020 22:15:48
User entered 'No (N)'	System	26 Aug 2020 22:15:48



US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-26T17:15:05', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '596524d0-6831-4c69-adb6-89b7e1395046'	System	26 Aug 2020 22:15:48
User entered 'No (N)'	System	26 Aug 2020 22:15:48

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-26T17:15:43', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '596524d0-6831-4c69-adb6-89b7e1395046'	System	26 Aug 2020 22:15:48
User entered 'None (1)'	System	26 Aug 2020 22:15:48

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-26T17:15:47', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '596524d0-6831-4c69-adb6-89b7e1395046'	System	26 Aug 2020 22:15:48
User entered '26 Aug 2020 17:15'	System	26 Aug 2020 22:15:48

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 3'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-27T12:45:48', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '5f893590-c328-4a1e-913c-c57039f2ab25'	System	27 Aug 2020 17:46:18
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 17:46:18

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:32:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-27T12:46:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '5f893590-c328-4a1e-913c-c57039f2ab25'	System	27 Aug 2020 17:46:18
User entered 'No (N)'	System	27 Aug 2020 17:46:18



US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-27T12:46:04', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '5f893590-c328-4a1e-913c-c57039f2ab25'	System	27 Aug 2020 17:46:18
User entered 'No (N)'	System	27 Aug 2020 17:46:18

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-27T12:46:14', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '5f893590-c328-4a1e-913c-c57039f2ab25' User entered 'None (1)'	System	27 Aug 2020 17:46:18
	System	27 Aug 2020 17:46:18

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-27T12:46:16', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '5f893590-c328-4a1e-913c-c57039f2ab25' User entered '27 Aug 2020 12:46'	System	27 Aug 2020 17:46:18
	System	27 Aug 2020 17:46:18

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 4'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-28T12:47:29', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'c58aee8a-0660-4323-8f45-31716b68b007'	System	28 Aug 2020 17:48:01
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 17:48:01

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:32:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-28T12:47:36', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'c58aee8a-0660-4323-8f45-31716b68b007' User entered 'No (N)'	System	28 Aug 2020 17:48:01
	System	28 Aug 2020 17:48:01



US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-28T12:47:41', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'c58aee8a-0660-4323-8f45-31716b68b007' User entered 'No (N)'	System	28 Aug 2020 17:48:01
	System	28 Aug 2020 17:48:01

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-28T12:47:52', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'c58aee8a-0660-4323-8f45-31716b68b007' User entered 'None (1)'	System	28 Aug 2020 17:48:01
	System	28 Aug 2020 17:48:01

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-28T12:47:56', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'c58aee8a-0660-4323-8f45-31716b68b007' User entered '28 Aug 2020 12:47'	System	28 Aug 2020 17:48:01
	System	28 Aug 2020 17:48:01

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 5'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-30T09:07:19', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '448d571d-b331-4538-a4a8-8d6a6712a77a' User entered 'None (1)'	System	30 Aug 2020 14:07:59
	System	30 Aug 2020 14:07:59

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:32:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-30T09:07:37', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '448d571d-b331-4538-a4a8-8d6a6712a77a' User entered 'No (N)'	System	30 Aug 2020 14:07:59
	System	30 Aug 2020 14:07:59



US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-30T09:07:40', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '448d571d-b331-4538-a4a8-8d6a6712a77a' User entered 'No (N)'	System	30 Aug 2020 14:07:59
	System	30 Aug 2020 14:07:59

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-30T09:07:56', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '448d571d-b331-4538-a4a8-8d6a6712a77a' User entered 'None (1)'	System	30 Aug 2020 14:07:59
	System	30 Aug 2020 14:07:59

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-30T09:07:58', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '448d571d-b331-4538-a4a8-8d6a6712a77a' User entered '30 Aug 2020 09:07'	System	30 Aug 2020 14:07:59
	System	30 Aug 2020 14:07:59

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 6'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-31T09:41:11', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '18418b6c-1a7f-4c69-9757-58f42e3bf08f' User entered 'None (1)'	System	31 Aug 2020 14:43:53
	System	31 Aug 2020 14:43:53

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:32:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-31T09:41:18', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '18418b6c-1a7f-4c69-9757-58f42e3bf08f' User entered 'No (N)'	System	31 Aug 2020 14:43:53
	System	31 Aug 2020 14:43:53



US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-31T09:41:20', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '18418b6c-1a7f-4c69-9757-58f42e3bf08f' User entered 'No (N)'	System	31 Aug 2020 14:43:53
	System	31 Aug 2020 14:43:53

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-31T09:41:31', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '18418b6c-1a7f-4c69-9757-58f42e3bf08f' User entered 'None (1)'	System	31 Aug 2020 14:43:53
	System	31 Aug 2020 14:43:53

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-31T09:41:32', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '18418b6c-1a7f-4c69-9757-58f42e3bf08f' User entered '31 Aug 2020 09:41'	System	31 Aug 2020 14:43:53
	System	31 Aug 2020 14:43:53

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 7'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-01T09:27:04', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '17a9e4b8-2495-418d-97ab-790ffa13a934' User entered 'None (1)'	System	01 Sep 2020 14:27:18
	System	01 Sep 2020 14:27:18

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:32:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-01T09:27:07', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '17a9e4b8-2495-418d-97ab-790ffa13a934' User entered 'No (N)'	System	01 Sep 2020 14:27:18
	System	01 Sep 2020 14:27:18



US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-01T09:27:08', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '17a9e4b8-2495-418d-97ab-790ffa13a934' User entered 'No (N)'	System	01 Sep 2020 14:27:18
	System	01 Sep 2020 14:27:18

US3422101

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-01T09:27:14', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '17a9e4b8-2495-418d-97ab-790ffa13a934' User entered 'None (1)'	System	01 Sep 2020 14:27:18
	System	01 Sep 2020 14:27:18

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-01T09:27:16', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '17a9e4b8-2495-418d-97ab-790ffa13a934' User entered '01 Sep 2020 09:27'	System	01 Sep 2020 14:27:18
	System	01 Sep 2020 14:27:18

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T10:27:28', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a3383717-c45b-4f0b-b072-e7542cef34a2' User entered 'None (0)'	System	25 Aug 2020 15:27:48
	System	25 Aug 2020 15:27:48

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T10:27:30', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a3383717-c45b-4f0b-b072-e7542cef34a2' User entered 'None (0)'	System	25 Aug 2020 15:27:48
	System	25 Aug 2020 15:27:48



**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T10:27:32', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a3383717-c45b-4f0b-b072-e7542cef34a2' User entered 'None (0)'	System	25 Aug 2020 15:27:48
	System	25 Aug 2020 15:27:48

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T10:27:35', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a3383717-c45b-4f0b-b072-e7542cef34a2' User entered 'None (0)'	System	25 Aug 2020 15:27:48
	System	25 Aug 2020 15:27:48

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T10:27:37', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a3383717-c45b-4f0b-b072-e7542cef34a2' User entered 'None (0)'	System	25 Aug 2020 15:27:48
	System	25 Aug 2020 15:27:48

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T10:27:39', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a3383717-c45b-4f0b-b072-e7542cef34a2' User entered 'None (0)'	System	25 Aug 2020 15:27:48
	System	25 Aug 2020 15:27:48

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T10:27:44', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a3383717-c45b-4f0b-b072-e7542cef34a2'	System	25 Aug 2020 15:27:48
User entered 'No (N)'	System	25 Aug 2020 15:27:48

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T10:27:47', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a3383717-c45b-4f0b-b072-e7542cef34a2' User entered '25 Aug 2020 10:27'	System	25 Aug 2020 15:27:48
	System	25 Aug 2020 15:27:48

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '25 Aug 2020 10:12'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '25 Aug 2020 12:42'	System	25 Aug 2020 14:55:14



US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T14:40:25', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '9b76cb77-abf5-4e5f-b204-5a82d2a414ab' User entered 'None (0)'	System	25 Aug 2020 19:40:49
	System	25 Aug 2020 19:40:49

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T14:40:28', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '9b76cb77-abf5-4e5f-b204-5a82d2a414ab' User entered 'None (0)'	System	25 Aug 2020 19:40:49
	System	25 Aug 2020 19:40:49

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T14:40:31', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '9b76cb77-abf5-4e5f-b204-5a82d2a414ab' User entered 'None (0)'	System	25 Aug 2020 19:40:49
	System	25 Aug 2020 19:40:49

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T14:40:34', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '9b76cb77-abf5-4e5f-b204-5a82d2a414ab' User entered 'None (0)'	System	25 Aug 2020 19:40:49
	System	25 Aug 2020 19:40:49

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T14:40:36', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '9b76cb77-abf5-4e5f-b204-5a82d2a414ab' User entered 'None (0)'	System	25 Aug 2020 19:40:49
	System	25 Aug 2020 19:40:49

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T14:40:38', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '9b76cb77-abf5-4e5f-b204-5a82d2a414ab' User entered 'None (0)'	System	25 Aug 2020 19:40:49
	System	25 Aug 2020 19:40:49

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T14:40:42', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '9b76cb77-abf5-4e5f-b204-5a82d2a414ab' User entered 'No (N)'	System	25 Aug 2020 19:40:49
	System	25 Aug 2020 19:40:49



**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-25T14:40:44', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '9b76cb77-abf5-4e5f-b204-5a82d2a414ab' User entered '25 Aug 2020 14:40'	System	25 Aug 2020 19:40:49
	System	25 Aug 2020 19:40:49

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '25 Aug 2020 13:37'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 2'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-26T17:15:52', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '7d47f7d2-64bb-4282-b1de-2cb486c81d6a' User entered 'None (0)'	System	26 Aug 2020 22:16:28
	System	26 Aug 2020 22:16:28

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-26T17:16:07', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '7d47f7d2-64bb-4282-b1de-2cb486c81d6a'	System	26 Aug 2020 22:16:28
User entered 'No interference with activity (1)'	System	26 Aug 2020 22:16:28

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:32:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-26T17:16:10', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '7d47f7d2-64bb-4282-b1de-2cb486c81d6a' User entered 'None (0)'	System	26 Aug 2020 22:16:28
	System	26 Aug 2020 22:16:28

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:32:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-26T17:16:13', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '7d47f7d2-64bb-4282-b1de-2cb486c81d6a' User entered 'None (0)'	System	26 Aug 2020 22:16:28
	System	26 Aug 2020 22:16:28



**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-26T17:16:15', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '7d47f7d2-64bb-4282-b1de-2cb486c81d6a' User entered 'None (0)'	System	26 Aug 2020 22:16:28
	System	26 Aug 2020 22:16:28

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-26T17:16:16', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '7d47f7d2-64bb-4282-b1de-2cb486c81d6a' User entered 'None (0)'	System	26 Aug 2020 22:16:28
	System	26 Aug 2020 22:16:28

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-26T17:16:24', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '7d47f7d2-64bb-4282-b1de-2cb486c81d6a' User entered 'No (N)'	System	26 Aug 2020 22:16:28
	System	26 Aug 2020 22:16:28

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-26T17:16:26', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '7d47f7d2-64bb-4282-b1de-2cb486c81d6a' User entered '26 Aug 2020 17:16'	System	26 Aug 2020 22:16:28
	System	26 Aug 2020 22:16:28

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 3'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-27T12:46:20', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '591d2820-8eaa-4bd8-a377-074330cedea5' User entered 'None (0)'	System	27 Aug 2020 17:46:39
	System	27 Aug 2020 17:46:39



**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-27T12:46:24', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '591d2820-8eaa-4bd8-a377-074330cedea5' User entered 'None (0)'	System	27 Aug 2020 17:46:39
	System	27 Aug 2020 17:46:39

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:32:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-27T12:46:26', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '591d2820-8eaa-4bd8-a377-074330cedea5' User entered 'None (0)'	System	27 Aug 2020 17:46:39
	System	27 Aug 2020 17:46:39

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:32:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-27T12:46:28', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '591d2820-8eaa-4bd8-a377-074330cedea5' User entered 'None (0)'	System	27 Aug 2020 17:46:39
	System	27 Aug 2020 17:46:39

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:32:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-27T12:46:30', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '591d2820-8eaa-4bd8-a377-074330cedea5' User entered 'None (0)'	System	27 Aug 2020 17:46:39
	System	27 Aug 2020 17:46:39

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:32:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-27T12:46:31', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '591d2820-8eaa-4bd8-a377-074330cedea5' User entered 'None (0)'	System	27 Aug 2020 17:46:39
	System	27 Aug 2020 17:46:39

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-27T12:46:36', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '591d2820-8eaa-4bd8-a377-074330cedea5' User entered 'No (N)'	System	27 Aug 2020 17:46:39
	System	27 Aug 2020 17:46:39

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-27T12:46:37', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '591d2820-8eaa-4bd8-a377-074330cedea5' User entered '27 Aug 2020 12:46'	System	27 Aug 2020 17:46:39
	System	27 Aug 2020 17:46:39

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 14:55:14



**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 4'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:32:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-28T12:48:04', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'e3574af1-38c5-46eb-af5f-c25dab48edf3' User entered 'None (0)'	System	28 Aug 2020 17:48:18
	System	28 Aug 2020 17:48:18

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-28T12:48:06', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'e3574af1-38c5-46eb-af5f-c25dab48edf3' User entered 'None (0)'	System	28 Aug 2020 17:48:18
	System	28 Aug 2020 17:48:18

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:32:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-28T12:48:07', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'e3574af1-38c5-46eb-af5f-c25dab48edf3' User entered 'None (0)'	System	28 Aug 2020 17:48:18
	System	28 Aug 2020 17:48:18

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:32:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-28T12:48:09', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'e3574af1-38c5-46eb-af5f-c25dab48edf3' User entered 'None (0)'	System	28 Aug 2020 17:48:18
	System	28 Aug 2020 17:48:18

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-28T12:48:10', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'e3574af1-38c5-46eb-af5f-c25dab48edf3' User entered 'None (0)'	System	28 Aug 2020 17:48:18
	System	28 Aug 2020 17:48:18

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:32:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-28T12:48:12', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'e3574af1-38c5-46eb-af5f-c25dab48edf3' User entered 'None (0)'	System	28 Aug 2020 17:48:18
	System	28 Aug 2020 17:48:18



US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-28T12:48:15', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'e3574af1-38c5-46eb-af5f-c25dab48edf3'	System	28 Aug 2020 17:48:18
User entered 'No (N)'	System	28 Aug 2020 17:48:18

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-28T12:48:16', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'e3574af1-38c5-46eb-af5f-c25dab48edf3' User entered '28 Aug 2020 12:48'	System	28 Aug 2020 17:48:18
	System	28 Aug 2020 17:48:18

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 5'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-30T09:08:03', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '509ec604-7ecc-43e6-acae-c740e89b7008' User entered 'None (0)'	System	30 Aug 2020 14:08:27
	System	30 Aug 2020 14:08:27

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:32:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-30T09:08:05', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '509ec604-7ecc-43e6-acae-c740e89b7008' User entered 'None (0)'	System	30 Aug 2020 14:08:27
	System	30 Aug 2020 14:08:27

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:32:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-30T09:08:07', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '509ec604-7ecc-43e6-acae-c740e89b7008' User entered 'None (0)'	System	30 Aug 2020 14:08:27
	System	30 Aug 2020 14:08:27



US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:32:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-30T09:08:08', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '509ec604-7ecc-43e6-acae-c740e89b7008' User entered 'None (0)'	System	30 Aug 2020 14:08:27
	System	30 Aug 2020 14:08:27

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-30T09:08:10', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '509ec604-7ecc-43e6-acae-c740e89b7008' User entered 'None (0)'	System	30 Aug 2020 14:08:27
	System	30 Aug 2020 14:08:27

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-30T09:08:12', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '509ec604-7ecc-43e6-acae-c740e89b7008' User entered 'None (0)'	System	30 Aug 2020 14:08:27
	System	30 Aug 2020 14:08:27

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-30T09:08:22', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '509ec604-7ecc-43e6-acae-c740e89b7008' User entered 'No (N)'	System	30 Aug 2020 14:08:27
	System	30 Aug 2020 14:08:27

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-30T09:08:25', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '509ec604-7ecc-43e6-acae-c740e89b7008' User entered '30 Aug 2020 09:08'	System	30 Aug 2020 14:08:27
	System	30 Aug 2020 14:08:27

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 6'	System	25 Aug 2020 14:55:14



**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-31T09:41:41', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'fc3e0ce8-8308-4e5a-bd4b-8a5f1778dc9f' User entered 'None (0)'	System	31 Aug 2020 14:44:13
	System	31 Aug 2020 14:44:13

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-31T09:41:57', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'fc3e0ce8-8308-4e5a-bd4b-8a5f1778dc9f' User entered 'None (0)'	System	31 Aug 2020 14:44:13
	System	31 Aug 2020 14:44:13

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-31T09:41:59', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'fc3e0ce8-8308-4e5a-bd4b-8a5f1778dc9f' User entered 'None (0)'	System	31 Aug 2020 14:44:13
	System	31 Aug 2020 14:44:13

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-31T09:42:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'fc3e0ce8-8308-4e5a-bd4b-8a5f1778dc9f' User entered 'None (0)'	System	31 Aug 2020 14:44:13
	System	31 Aug 2020 14:44:13

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-31T09:42:02', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'fc3e0ce8-8308-4e5a-bd4b-8a5f1778dc9f' User entered 'None (0)'	System	31 Aug 2020 14:44:13
	System	31 Aug 2020 14:44:13

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-31T09:42:04', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'fc3e0ce8-8308-4e5a-bd4b-8a5f1778dc9f' User entered 'None (0)'	System	31 Aug 2020 14:44:13
	System	31 Aug 2020 14:44:13

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-31T09:42:07', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'fc3e0ce8-8308-4e5a-bd4b-8a5f1778dc9f' User entered 'No (N)'	System	31 Aug 2020 14:44:13
	System	31 Aug 2020 14:44:13

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-08-31T09:42:09', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'fc3e0ce8-8308-4e5a-bd4b-8a5f1778dc9f' User entered '31 Aug 2020 09:42'	System	31 Aug 2020 14:44:13
	System	31 Aug 2020 14:44:13



**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 14:55:14

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 7'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-01T09:27:37', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '4a6e3332-3b79-4fab-b5f6-f2ba72aed9e7'	System	01 Sep 2020 14:28:04
User entered 'No interference with activity (1)'	System	01 Sep 2020 14:28:04

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:32:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-01T09:27:46', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '4a6e3332-3b79-4fab-b5f6-f2ba72aed9e7'	System	01 Sep 2020 14:28:04
User entered 'No interference with activity (1)'	System	01 Sep 2020 14:28:04

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-01T09:27:47', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '4a6e3332-3b79-4fab-b5f6-f2ba72aed9e7' User entered 'None (0)'	System	01 Sep 2020 14:28:04
	System	01 Sep 2020 14:28:04

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:32:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-01T09:27:49', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '4a6e3332-3b79-4fab-b5f6-f2ba72aed9e7' User entered 'None (0)'	System	01 Sep 2020 14:28:04
	System	01 Sep 2020 14:28:04

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-01T09:27:50', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '4a6e3332-3b79-4fab-b5f6-f2ba72aed9e7' User entered 'None (0)'	System	01 Sep 2020 14:28:04
	System	01 Sep 2020 14:28:04



**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-01T09:27:52', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '4a6e3332-3b79-4fab-b5f6-f2ba72aed9e7' User entered 'None (0)'	System	01 Sep 2020 14:28:04
	System	01 Sep 2020 14:28:04

US3422101

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-01T09:27:54', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '4a6e3332-3b79-4fab-b5f6-f2ba72aed9e7' User entered 'No (N)'	System	01 Sep 2020 14:28:04
	System	01 Sep 2020 14:28:04

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-01T09:27:59', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '4a6e3332-3b79-4fab-b5f6-f2ba72aed9e7' User entered '01 Sep 2020 09:27'	System	01 Sep 2020 14:28:04
	System	01 Sep 2020 14:28:04

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	01 Sep 2020 14:28:04
User entered 'Day 8'	System	01 Sep 2020 14:28:04

US3422101

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37



**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '01 Sep 2020 12:00'	System	01 Sep 2020 14:28:04

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 14:28:04

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	01 Sep 2020 14:28:04
User entered 'Day 9'	System	01 Sep 2020 14:28:04

US3422101

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-02T17:59:22', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '85f736ec-0143-43ef-b461-9d64831fefef' User entered 'No interference with activity (1)'	System	02 Sep 2020 22:59:27
	System	02 Sep 2020 22:59:27

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-02T17:59:24', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '85f736ec-0143-43ef-b461-9d64831fefef' User entered '02 Sep 2020 17:59'	System	02 Sep 2020 22:59:27
	System	02 Sep 2020 22:59:27

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 14:28:04

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 14:28:04

US3422101

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	02 Sep 2020 22:59:27
User entered 'Day 10'	System	02 Sep 2020 22:59:27



**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(10)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-03T12:05:49', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '926906b9-985c-4412-9d5c-7fee68b5d2f0'	System	03 Sep 2020 17:05:53
User entered 'No interference with activity (1)'	System	03 Sep 2020 17:05:53

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(10)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-03T12:05:51', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '926906b9-985c-4412-9d5c-7fee68b5d2f0' User entered '03 Sep 2020 12:05'	System	03 Sep 2020 17:05:53
	System	03 Sep 2020 17:05:53

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(10)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:59:27

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(10)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:59:27

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(11)**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	02 Sep 2020 22:59:27
User entered 'Day 11'	System	02 Sep 2020 22:59:27

US3422101

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-04T15:51:18', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '047e701a-288f-45bc-ace4-177de40a4bdd' User entered 'None (0)'	System	04 Sep 2020 20:51:22
	System	04 Sep 2020 20:51:22

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(11)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-04T15:51:19', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '047e701a-288f-45bc-ace4-177de40a4bdd' User entered '04 Sep 2020 15:51'	System	04 Sep 2020 20:51:22
	System	04 Sep 2020 20:51:22

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(11)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:59:27



**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(11)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:59:27

US3422101

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	01 Sep 2020 14:28:04
User entered 'Day 8'	System	01 Sep 2020 14:28:04

US3422101

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '01 Sep 2020 12:00'	System	01 Sep 2020 14:28:04

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 14:28:04

US3422101

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	01 Sep 2020 14:28:04
User entered 'Day 9'	System	01 Sep 2020 14:28:04

US3422101

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-02T17:59:31', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'd37d8a2c-5429-4aa6-9d28-231572e15781' User entered 'None (0)'	System	02 Sep 2020 22:59:37
	System	02 Sep 2020 22:59:37



**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-02T17:59:33', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'd37d8a2c-5429-4aa6-9d28-231572e15781' User entered '02 Sep 2020 17:59'	System	02 Sep 2020 22:59:37
	System	02 Sep 2020 22:59:37

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 14:28:04

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(9)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 14:28:04

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	01 Sep 2020 14:28:04
User entered 'Day 8'	System	01 Sep 2020 14:28:04

US3422101

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '01 Sep 2020 12:00'	System	01 Sep 2020 14:28:04

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 14:28:04



**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	01 Sep 2020 14:28:04
User entered 'Day 9'	System	01 Sep 2020 14:28:04

US3422101

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-02T17:59:52', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'dbbe66f8-70a4-4116-a860-3e4b5bf93656' User entered 'Yes (Y)'	System	02 Sep 2020 23:00:09
	System	02 Sep 2020 23:00:09

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-02T18:00:02', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'dbbe66f8-70a4-4116-a860-3e4b5bf93656' User entered '02 Sep 2020 18:00'	System	02 Sep 2020 23:00:09
	System	02 Sep 2020 23:00:09

US3422101

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:32:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 14:28:04

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 14:28:04

US3422101

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	02 Sep 2020 22:59:27
User entered 'Day 11'	System	02 Sep 2020 22:59:27

US3422101

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-04T15:51:26', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'cdf8e27a-5789-433e-b882-05e07682acb0' User entered 'No (N)'	System	04 Sep 2020 20:51:31
	System	04 Sep 2020 20:51:31

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-04T15:51:29', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'cdf8e27a-5789-433e-b882-05e07682acb0' User entered '04 Sep 2020 15:51'	System	04 Sep 2020 20:51:31
	System	04 Sep 2020 20:51:31



**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:59:27

**US3422101**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:59:27

**US3422101**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	01 Sep 2020 19:37:36

**US3422101**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '1 Sep 2020'	Cindy Trimmer (b) (4)	01 Sep 2020 19:37:36

**US3422101**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Contact Made (CONTACT MADE)'	Cindy Trimmer (b) (4)	01 Sep 2020 19:37:36

**US3422101**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	Cindy Trimmer (b) (4)	01 Sep 2020 19:37:36

**US3422101**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	01 Sep 2020 19:37:40

**US3422101**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'I'	System	01 Sep 2020 19:37:40



**US3422101**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	08 Sep 2020 19:59:11

**US3422101**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '8 Sep 2020'	Cindy Trimmer (b) (4)	08 Sep 2020 19:59:11

**US3422101**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Contact Made (CONTACT MADE)'	Cindy Trimmer (b) (4)	08 Sep 2020 19:59:11

**US3422101**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	Cindy Trimmer (b) (4)	08 Sep 2020 19:59:11

**US3422101**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	08 Sep 2020 19:59:16

**US3422101**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'I'	System	08 Sep 2020 19:59:16

**US3422101**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	15 Sep 2020 16:11:59

**US3422101**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '15 Sep 2020'	Cindy Trimmer (b) (4)	15 Sep 2020 16:11:59



**US3422101**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Contact Made (CONTACT MADE)'	Cindy Trimmer (b) (4)	15 Sep 2020 16:11:59

**US3422101**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	Cindy Trimmer (b) (4)	15 Sep 2020 16:11:59

**US3422101**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	15 Sep 2020 16:12:06

**US3422101**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'I'	System	15 Sep 2020 16:12:06

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:44:07

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:44:07

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:44:07

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'VISIT2'	System	22 Sep 2020 13:44:07



US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Sep 2020 17:58:58

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:58:58

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:32:16**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 17:58:58

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '07:58'	(b) (4), (b) (6)	22 Sep 2020 17:58:58

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered '22 Sep 2020 07:58'	System	22 Sep 2020 17:58:58

US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '098.6' F	(b) (4), (b) (6)	22 Sep 2020 17:58:58

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:58:58

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:32:16**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 17:58:58



**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '079'	(b) (4), (b) (6)	22 Sep 2020 17:58:58

US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'bpm'	System	22 Sep 2020 17:58:58

US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '14'	(b) (4), (b) (6)	22 Sep 2020 17:58:58

US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'breaths/min'	System	22 Sep 2020 17:58:58

US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '122'	(b) (4), (b) (6)	22 Sep 2020 17:58:58

US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'mmHg'	System	22 Sep 2020 17:58:58

US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '088'	(b) (4), (b) (6)	22 Sep 2020 17:58:58

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'mmHg'	System	22 Sep 2020 17:58:58



US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Sep 2020 17:58:58

US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Sep 2020 19:42:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 19:42:40
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	22 Sep 2020 19:42:40
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 17:58:58
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 17:58:58

US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '22 Sep 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Sep 2020 19:42:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 17:58:58

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '09:09' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Sep 2020 19:42:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 17:58:58

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered '22 Sep 2020 09:09'	System	22 Sep 2020 19:42:40
User entered empty.	System	22 Sep 2020 17:58:58

US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '097.5' F reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Sep 2020 19:42:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 17:58:58

US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Sep 2020 19:43:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Sep 2020 19:43:36
User entered 'Oral (Oral)' reason for change: New Information	(b) (4), (b) (6)	22 Sep 2020 19:43:36
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 19:42:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 17:58:58

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:32:16**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 17:58:58



US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Sep 2020 19:43:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Sep 2020 19:43:36
User entered '074' reason for change: New Information	(b) (4), (b) (6)	22 Sep 2020 19:43:36
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 19:42:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 17:58:58

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'bpm'	System	22 Sep 2020 19:43:36
User entered empty.	System	22 Sep 2020 17:58:58

US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Sep 2020 19:43:36
Query 'Data is required. Please provide.' answered by System	System	22 Sep 2020 19:43:36
data change (Site from System).		
User entered '12' reason for change: New Information	(b) (4), (b) (6)	22 Sep 2020 19:43:36
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 19:42:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 17:58:58

US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'breaths/min'	System	22 Sep 2020 19:43:36
User entered empty.	System	22 Sep 2020 17:58:58

US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Sep 2020 19:43:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Sep 2020 19:43:36
User entered '118' reason for change: New Information	(b) (4), (b) (6)	22 Sep 2020 19:43:36
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 19:42:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 17:58:58

US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'mmHg'	System	22 Sep 2020 19:43:36
User entered empty.	System	22 Sep 2020 17:58:58

US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Sep 2020 19:43:36
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Sep 2020 19:43:36
User entered '074' reason for change: New Information	(b) (4), (b) (6)	22 Sep 2020 19:43:36
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 19:42:40
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 17:58:58

US3422101

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'mmHg'	System	22 Sep 2020 19:43:36
User entered empty.	System	22 Sep 2020 17:58:58



**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:32:16**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:59:19

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:32:16**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 17:59:19

US3422101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:32:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:00

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:32:16**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:19:00

US3422101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:19:00

US3422101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:32:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 14:19:00

US3422101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:32:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:00

US3422101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '08:39'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:00



**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered '22 Sep 2020 08:39'	System	22 Sep 2020 14:19:00

US3422101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 14:19:00

US3422101

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:32:16

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'ONCE'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:32:16**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:00:19

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:32:16**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:00:19

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:32:16**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '08:01'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:00:19

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered '22 Sep 2020 08:01'	System	22 Sep 2020 18:00:19



**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 17:32:16**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:01:02

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	22 Sep 2020 18:01:02

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:01:02

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '07:59'	(b) (4), (b) (6)	22 Sep 2020 18:01:02

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered '22 Sep 2020 07:59'	System	22 Sep 2020 18:01:02

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	22 Sep 2020 18:01:02

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:01:02

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:01:02



**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered empty.	System	22 Sep 2020 18:01:02

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:01:05

**US3422101**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'I'	System	22 Sep 2020 18:01:05

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 14:19:00

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T09:19:20', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '2974300e-bb1d-4bf5-9793-e98abadd6562' User entered 'Yes (Y)'	System	22 Sep 2020 14:19:38
	System	22 Sep 2020 14:19:38

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T09:19:24', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '2974300e-bb1d-4bf5-9793-e98abadd6562' User entered '97.5'	System	22 Sep 2020 14:19:38
	System	22 Sep 2020 14:19:38

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T09:19:29', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '2974300e-bb1d-4bf5-9793-e98abadd6562'	System	22 Sep 2020 14:19:38
User entered 'No (N)'	System	22 Sep 2020 14:19:38

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T09:19:31', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '2974300e-bb1d-4bf5-9793-e98abadd6562'	System	22 Sep 2020 14:19:38
User entered '22 Sep 2020 09:19'	System	22 Sep 2020 14:19:38



**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '22 Sep 2020 08:59'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '22 Sep 2020 11:29'	System	22 Sep 2020 14:19:00

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T18:16:51', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'beea2131-e2d0-4836-ae9-f8280c06910b' User entered 'Yes (Y)'	System	22 Sep 2020 23:17:18
	System	22 Sep 2020 23:17:18

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T18:16:56', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'beea2131-e2d0-4836-ae9-f8280c06910b' User entered '98.2'	System	22 Sep 2020 23:17:18
	System	22 Sep 2020 23:17:18

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T18:17:01', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'beea2131-e2d0-4836-ae9-f8280c06910b' User entered 'Yes (Y)'	System	22 Sep 2020 23:17:18
	System	22 Sep 2020 23:17:18

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
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 'participant contacted' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 04:34:13
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.'	Naomi Kown (b) (4)	23 Sep 2020 18:11:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T18:17:13', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'beea2131-e2d0-4836-ae9-f8280c06910b'	System	22 Sep 2020 23:17:18
User entered '1'	System	22 Sep 2020 23:17:18

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T18:17:13', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'beea2131-e2d0-4836-ae9-f8280c06910b' User entered '0'	System	22 Sep 2020 23:17:18
	System	22 Sep 2020 23:17:18



**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T18:17:15', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'beea2131-e2d0-4836-ae9-f8280c06910b' User entered '22 Sep 2020 18:17'	System	22 Sep 2020 23:17:18
	System	22 Sep 2020 23:17:18

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '22 Sep 2020 12:24'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 14:19:00

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 2'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-23T13:10:36', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '79c2da6f-2e70-4f9d-9eb2-dfd142cdce6b' User entered 'Yes (Y)'	System	23 Sep 2020 18:11:12
	System	23 Sep 2020 18:11:12

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:32:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-23T13:10:43', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '79c2da6f-2e70-4f9d-9eb2-dfd142cdce6b' User entered '99.8'	System	23 Sep 2020 18:11:12
	System	23 Sep 2020 18:11:12

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-23T13:10:59', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '79c2da6f-2e70-4f9d-9eb2-dfd142cdce6b' User entered 'Yes (Y)'	System	23 Sep 2020 18:11:12
	System	23 Sep 2020 18:11:12

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
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 'participant contacted' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 04:34:08
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).	Naomi Kown (b) (4)	23 Sep 2020 18:30:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-23T13:11:08', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '79c2da6f-2e70-4f9d-9eb2-dfd142cdce6b'	(b) (4)	
User entered '1'	System	23 Sep 2020 18:11:12
	System	23 Sep 2020 18:11:12
	System	23 Sep 2020 18:11:12



US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:32:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-23T13:11:08', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '79c2da6f-2e70-4f9d-9eb2-dfd142cdce6b' User entered '0'	System	23 Sep 2020 18:11:12
	System	23 Sep 2020 18:11:12

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-23T13:11:10', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '79c2da6f-2e70-4f9d-9eb2-dfd142cdce6b' User entered '23 Sep 2020 13:11'	System	23 Sep 2020 18:11:12
	System	23 Sep 2020 18:11:12

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 14:19:00

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 3'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-24T13:22:15', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '9640091f-6c0a-4deb-ae02-1ee9bf3e4143' User entered 'Yes (Y)'	System	24 Sep 2020 18:22:32
	System	24 Sep 2020 18:22:32

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:32:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-24T13:22:19', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '9640091f-6c0a-4deb-ae02-1ee9bf3e4143' User entered '98.2'	System	24 Sep 2020 18:22:32
	System	24 Sep 2020 18:22:32

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-24T13:22:26', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '9640091f-6c0a-4deb-ae02-1ee9bf3e4143'	System	24 Sep 2020 18:22:32
User entered 'No (N)'	System	24 Sep 2020 18:22:32



**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-24T13:22:28', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '9640091f-6c0a-4deb-ae02-1ee9bf3e4143' User entered '24 Sep 2020 13:22'	System	24 Sep 2020 18:22:32
	System	24 Sep 2020 18:22:32

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 14:19:00

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 4'	System	22 Sep 2020 14:19:00

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:32:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-25T15:14:11', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '41318362-8773-43e9-9f3b-ebc17d3efd44'	System	25 Sep 2020 20:14:51
User entered 'Yes (Y)'	System	25 Sep 2020 20:14:51

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:32:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-25T15:14:15', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '41318362-8773-43e9-9f3b-ebc17d3efd44' User entered '98.4'	System	25 Sep 2020 20:14:51
	System	25 Sep 2020 20:14:51

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-25T15:14:17', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '41318362-8773-43e9-9f3b-ebc17d3efd44'	System	25 Sep 2020 20:14:51
User entered 'No (N)'	System	25 Sep 2020 20:14:51

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-25T15:14:49', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '41318362-8773-43e9-9f3b-ebc17d3efd44'	System	25 Sep 2020 20:14:51
User entered '25 Sep 2020 15:14'	System	25 Sep 2020 20:14:51



US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:32:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 14:19:00

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 5'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-26T21:26:08', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '20a3ecfb-bc2f-48ff-8d5c-bdeaa09d2678' User entered 'Yes (Y)'	System	27 Sep 2020 02:26:23
	System	27 Sep 2020 02:26:23

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:32:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-26T21:26:12', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '20a3ecfb-bc2f-48ff-8d5c-bdeaa09d2678' User entered '98.2'	System	27 Sep 2020 02:26:23
	System	27 Sep 2020 02:26:23

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-26T21:26:15', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '20a3ecfb-bc2f-48ff-8d5c-bdeaa09d2678' User entered 'No (N)'	System	27 Sep 2020 02:26:23

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-26T21:26:17', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '20a3ecfb-bc2f-48ff-8d5c-bdeaa09d2678' User entered '26 Sep 2020 21:26'	System	27 Sep 2020 02:26:23
	System	27 Sep 2020 02:26:23

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 14:19:00



**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 14:19:00

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 6'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-27T15:48:37', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ceb757d3-197b-42b1-a7b0-e3efa862045a' User entered 'Yes (Y)'	System	27 Sep 2020 20:48:46
	System	27 Sep 2020 20:48:46

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:32:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-27T15:48:41', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ceb757d3-197b-42b1-a7b0-e3efa862045a' User entered '98.0'	System	27 Sep 2020 20:48:46
	System	27 Sep 2020 20:48:46

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-27T15:48:43', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ceb757d3-197b-42b1-a7b0-e3efa862045a' User entered 'No (N)'	System	27 Sep 2020 20:48:46
	System	27 Sep 2020 20:48:46

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-27T15:48:44', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ceb757d3-197b-42b1-a7b0-e3efa862045a' User entered '27 Sep 2020 15:48'	System	27 Sep 2020 20:48:46
	System	27 Sep 2020 20:48:46

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 14:19:00

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:32:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 14:19:00



US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 7'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-28T15:48:38', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '4093992f-ad97-4f52-944e-91e1c6d8c803'	System	28 Sep 2020 20:48:52
User entered 'Yes (Y)'	System	28 Sep 2020 20:48:52

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:32:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-28T15:48:42', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '4093992f-ad97-4f52-944e-91e1c6d8c803' User entered '97.3'	System	28 Sep 2020 20:48:52
	System	28 Sep 2020 20:48:52

US3422101

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-28T15:48:44', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '4093992f-ad97-4f52-944e-91e1c6d8c803'	System	28 Sep 2020 20:48:52
User entered 'No (N)'	System	28 Sep 2020 20:48:52

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-28T15:48:46', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '4093992f-ad97-4f52-944e-91e1c6d8c803' User entered '28 Sep 2020 15:48'	System	28 Sep 2020 20:48:52
	System	28 Sep 2020 20:48:52

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 14:19:00



US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T09:19:38', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '0dae9535-8d10-4421-8041-ca483dfeea1f' User entered 'None (1)'	System	22 Sep 2020 14:20:16
	System	22 Sep 2020 14:20:16

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T09:19:50', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '0dae9535-8d10-4421-8041-ca483dfeea1f' User entered 'No (N)'	System	22 Sep 2020 14:20:16
	System	22 Sep 2020 14:20:16

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T09:19:58', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '0dae9535-8d10-4421-8041-ca483dfeea1f' User entered 'No (N)'	System	22 Sep 2020 14:20:16
	System	22 Sep 2020 14:20:16

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T09:20:10', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '0dae9535-8d10-4421-8041-ca483dfeea1f' User entered 'None (1)'	System	22 Sep 2020 14:20:16
	System	22 Sep 2020 14:20:16

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T09:20:14', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '0dae9535-8d10-4421-8041-ca483dfeea1f' User entered '22 Sep 2020 09:20'	System	22 Sep 2020 14:20:16
	System	22 Sep 2020 14:20:16

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '22 Sep 2020 08:59'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '22 Sep 2020 11:29'	System	22 Sep 2020 14:19:00

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 14:19:00



US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T18:17:24', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a6590d3e-e3ff-4abe-a6ff-f09070919d19'	System	22 Sep 2020 23:18:00
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 23:18:00

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T18:17:49', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a6590d3e-e3ff-4abe-a6ff-f09070919d19'	System	22 Sep 2020 23:18:00
User entered 'No (N)'	System	22 Sep 2020 23:18:00

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T18:17:51', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a6590d3e-e3ff-4abe-a6ff-f09070919d19'	System	22 Sep 2020 23:18:00
User entered 'No (N)'	System	22 Sep 2020 23:18:00

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T18:17:55', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a6590d3e-e3ff-4abe-a6ff-f09070919d19'	System	22 Sep 2020 23:18:00
User entered 'None (1)'	System	22 Sep 2020 23:18:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T18:17:56', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a6590d3e-e3ff-4abe-a6ff-f09070919d19'	System	22 Sep 2020 23:18:00
User entered '22 Sep 2020 18:17'	System	22 Sep 2020 23:18:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '22 Sep 2020 12:24'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 14:19:00

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 2'	System	22 Sep 2020 14:19:00



US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-23T13:11:41', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'c3e7e833-127d-4efd-817d-47ae22e00198'	System	23 Sep 2020 18:12:24
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	23 Sep 2020 18:12:24

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:32:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-23T13:11:52', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'c3e7e833-127d-4efd-817d-47ae22e00198' User entered 'No (N)'	System	23 Sep 2020 18:12:24
	System	23 Sep 2020 18:12:24

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-23T13:11:54', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'c3e7e833-127d-4efd-817d-47ae22e00198'	System	23 Sep 2020 18:12:24
User entered 'No (N)'	System	23 Sep 2020 18:12:24

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-23T13:11:57', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'c3e7e833-127d-4efd-817d-47ae22e00198'	System	23 Sep 2020 18:12:24
User entered 'None (1)'	System	23 Sep 2020 18:12:24

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-23T13:11:59', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'c3e7e833-127d-4efd-817d-47ae22e00198' User entered '23 Sep 2020 13:11'	System	23 Sep 2020 18:12:24
	System	23 Sep 2020 18:12:24

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 14:19:00

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 3'	System	22 Sep 2020 14:19:00



US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-24T13:22:32', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '271bfcc5-03c8-43c9-9905-f1381ce02868'	System	24 Sep 2020 18:22:48
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 18:22:48

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-24T13:22:34', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '271bfcc5-03c8-43c9-9905-f1381ce02868' User entered 'No (N)'	System	24 Sep 2020 18:22:48
	System	24 Sep 2020 18:22:48

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-24T13:22:36', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '271bfcc5-03c8-43c9-9905-f1381ce02868' User entered 'No (N)'	System	24 Sep 2020 18:22:48
	System	24 Sep 2020 18:22:48

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-24T13:22:44', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '271bfcc5-03c8-43c9-9905-f1381ce02868' User entered 'None (1)'	System	24 Sep 2020 18:22:48
	System	24 Sep 2020 18:22:48

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-24T13:22:45', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '271bfcc5-03c8-43c9-9905-f1381ce02868' User entered '24 Sep 2020 13:22'	System	24 Sep 2020 18:22:48
	System	24 Sep 2020 18:22:48

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 14:19:00

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 4'	System	22 Sep 2020 14:19:00



US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-25T15:15:13', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '234c8a19-1bbd-4ffe-86d0-7c79441f3471'	System	25 Sep 2020 20:15:28
User entered 'None (1)'	System	25 Sep 2020 20:15:28

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:32:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-25T15:15:16', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '234c8a19-1bbd-4ffe-86d0-7c79441f3471'	System	25 Sep 2020 20:15:28
User entered 'No (N)'	System	25 Sep 2020 20:15:28

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-25T15:15:20', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '234c8a19-1bbd-4ffe-86d0-7c79441f3471' User entered 'No (N)'	System	25 Sep 2020 20:15:28
	System	25 Sep 2020 20:15:28

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-25T15:15:23', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '234c8a19-1bbd-4ffe-86d0-7c79441f3471'	System	25 Sep 2020 20:15:28
User entered 'None (1)'	System	25 Sep 2020 20:15:28

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-25T15:15:25', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '234c8a19-1bbd-4ffe-86d0-7c79441f3471' User entered '25 Sep 2020 15:15'	System	25 Sep 2020 20:15:28
	System	25 Sep 2020 20:15:28

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 14:19:00

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 5'	System	22 Sep 2020 14:19:00



US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-26T21:26:24', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '842cd136-6427-47be-bb12-c4114c91eeec' User entered 'None (1)'	System	27 Sep 2020 02:26:40
	System	27 Sep 2020 02:26:40

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:32:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-26T21:26:26', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '842cd136-6427-47be-bb12-c4114c91eeec' User entered 'No (N)'	System	27 Sep 2020 02:26:40
	System	27 Sep 2020 02:26:40

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-26T21:26:28', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '842cd136-6427-47be-bb12-c4114c91eeec' User entered 'No (N)'	System	27 Sep 2020 02:26:40
	System	27 Sep 2020 02:26:40

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-26T21:26:35', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '842cd136-6427-47be-bb12-c4114c91eeec' User entered 'None (1)'	System	27 Sep 2020 02:26:40
	System	27 Sep 2020 02:26:40

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-26T21:26:37', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '842cd136-6427-47be-bb12-c4114c91eeec' User entered '26 Sep 2020 21:26'	System	27 Sep 2020 02:26:40
	System	27 Sep 2020 02:26:40

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 14:19:00

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 6'	System	22 Sep 2020 14:19:00



US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-27T15:48:50', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ad526e64-a15c-4567-b8b1-1c306564038a' User entered 'None (1)'	System	27 Sep 2020 20:49:09
	System	27 Sep 2020 20:49:09

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:32:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-27T15:49:01', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ad526e64-a15c-4567-b8b1-1c306564038a' User entered 'No (N)'	System	27 Sep 2020 20:49:09
	System	27 Sep 2020 20:49:09

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-27T15:49:03', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ad526e64-a15c-4567-b8b1-1c306564038a' User entered 'No (N)'	System	27 Sep 2020 20:49:09
	System	27 Sep 2020 20:49:09

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-27T15:49:05', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ad526e64-a15c-4567-b8b1-1c306564038a' User entered 'None (1)'	System	27 Sep 2020 20:49:09
	System	27 Sep 2020 20:49:09

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-27T15:49:07', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ad526e64-a15c-4567-b8b1-1c306564038a' User entered '27 Sep 2020 15:49'	System	27 Sep 2020 20:49:09
	System	27 Sep 2020 20:49:09

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 14:19:00

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 7'	System	22 Sep 2020 14:19:00



US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-28T15:48:56', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '4a524de1-c34b-41cb-9962-f6ef806ab2a1' User entered 'None (1)'	System	28 Sep 2020 20:49:06
	System	28 Sep 2020 20:49:06

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:32:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-28T15:48:57', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '4a524de1-c34b-41cb-9962-f6ef806ab2a1' User entered 'No (N)'	System	28 Sep 2020 20:49:06
	System	28 Sep 2020 20:49:06

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-28T15:49:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '4a524de1-c34b-41cb-9962-f6ef806ab2a1' User entered 'No (N)'	System	28 Sep 2020 20:49:06
	System	28 Sep 2020 20:49:06

US3422101

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:32:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-28T15:49:01', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '4a524de1-c34b-41cb-9962-f6ef806ab2a1' User entered 'None (1)'	System	28 Sep 2020 20:49:06
	System	28 Sep 2020 20:49:06

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-28T15:49:03', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '4a524de1-c34b-41cb-9962-f6ef806ab2a1' User entered '28 Sep 2020 15:49'	System	28 Sep 2020 20:49:06
	System	28 Sep 2020 20:49:06

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 14:19:00



**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T09:20:19', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'aa43c8a4-67f2-4233-ae5d-e72f188b17dc' User entered 'None (0)'	System	22 Sep 2020 14:20:37
	System	22 Sep 2020 14:20:37

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T09:20:21', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'aa43c8a4-67f2-4233-ae5d-e72f188b17dc' User entered 'None (0)'	System	22 Sep 2020 14:20:37
	System	22 Sep 2020 14:20:37

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T09:20:24', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'aa43c8a4-67f2-4233-ae5d-e72f188b17dc' User entered 'None (0)'	System	22 Sep 2020 14:20:37
	System	22 Sep 2020 14:20:37

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T09:20:25', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'aa43c8a4-67f2-4233-ae5d-e72f188b17dc' User entered 'None (0)'	System	22 Sep 2020 14:20:37
	System	22 Sep 2020 14:20:37

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T09:20:27', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'aa43c8a4-67f2-4233-ae5d-e72f188b17dc' User entered 'None (0)'	System	22 Sep 2020 14:20:37
	System	22 Sep 2020 14:20:37

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T09:20:29', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'aa43c8a4-67f2-4233-ae5d-e72f188b17dc' User entered 'None (0)'	System	22 Sep 2020 14:20:37
	System	22 Sep 2020 14:20:37

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T09:20:32', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'aa43c8a4-67f2-4233-ae5d-e72f188b17dc'	System	22 Sep 2020 14:20:37
User entered 'No (N)'	System	22 Sep 2020 14:20:37

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T09:20:34', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'aa43c8a4-67f2-4233-ae5d-e72f188b17dc' User entered '22 Sep 2020 09:20'	System	22 Sep 2020 14:20:37
	System	22 Sep 2020 14:20:37



**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '22 Sep 2020 08:59'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '22 Sep 2020 11:29'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T18:18:02', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '7a83bdb1-4eed-4407-a027-44e13ea848dc'	System	22 Sep 2020 23:18:29
User entered 'No interference with activity (1)'	System	22 Sep 2020 23:18:29

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T18:18:06', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '7a83bdb1-4eed-4407-a027-44e13ea848dc'	System	22 Sep 2020 23:18:29
User entered 'No interference with activity (1)'	System	22 Sep 2020 23:18:29

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T18:18:12', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '7a83bdb1-4eed-4407-a027-44e13ea848dc'	System	22 Sep 2020 23:18:29
User entered 'No interference with activity (1)'	System	22 Sep 2020 23:18:29

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T18:18:15', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '7a83bdb1-4eed-4407-a027-44e13ea848dc' User entered 'None (0)'	System	22 Sep 2020 23:18:29
	System	22 Sep 2020 23:18:29

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T18:18:17', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '7a83bdb1-4eed-4407-a027-44e13ea848dc' User entered 'None (0)'	System	22 Sep 2020 23:18:29
	System	22 Sep 2020 23:18:29



**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T18:18:21', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '7a83bdb1-4eed-4407-a027-44e13ea848dc' User entered 'None (0)'	System	22 Sep 2020 23:18:29
	System	22 Sep 2020 23:18:29

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T18:18:24', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '7a83bdb1-4eed-4407-a027-44e13ea848dc' User entered 'No (N)'	System	22 Sep 2020 23:18:29
	System	22 Sep 2020 23:18:29

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-22T18:18:26', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '7a83bdb1-4eed-4407-a027-44e13ea848dc' User entered '22 Sep 2020 18:18'	System	22 Sep 2020 23:18:29
	System	22 Sep 2020 23:18:29

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '22 Sep 2020 12:24'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 2'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-23T13:12:09', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'c59cad8d-de70-4bbc-929b-f28184c5bb7b'	System	23 Sep 2020 18:12:41
User entered 'No interference with activity (1)'	System	23 Sep 2020 18:12:41

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-23T13:12:14', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'c59cad8d-de70-4bbc-929b-f28184c5bb7b' User entered 'No interference with activity (1)'	System	23 Sep 2020 18:12:41
	System	23 Sep 2020 18:12:41



**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-23T13:12:17', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'c59cad8d-de70-4bbc-929b-f28184c5bb7b'	System	23 Sep 2020 18:12:41
User entered 'No interference with activity (1)'	System	23 Sep 2020 18:12:41

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:32:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-23T13:12:21', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'c59cad8d-de70-4bbc-929b-f28184c5bb7b' User entered 'None (0)'	System	23 Sep 2020 18:12:41
	System	23 Sep 2020 18:12:41

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-23T13:12:23', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'c59cad8d-de70-4bbc-929b-f28184c5bb7b' User entered 'None (0)'	System	23 Sep 2020 18:12:41
	System	23 Sep 2020 18:12:41

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-23T13:12:25', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'c59cad8d-de70-4bbc-929b-f28184c5bb7b' User entered 'No interference with activity (1)'	System	23 Sep 2020 18:12:41
	System	23 Sep 2020 18:12:41

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-23T13:12:28', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'c59cad8d-de70-4bbc-929b-f28184c5bb7b' User entered 'No (N)'	System	23 Sep 2020 18:12:41
	System	23 Sep 2020 18:12:41

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-23T13:12:29', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'c59cad8d-de70-4bbc-929b-f28184c5bb7b' User entered '23 Sep 2020 13:12'	System	23 Sep 2020 18:12:41
	System	23 Sep 2020 18:12:41

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 14:19:00



**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 3'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-24T13:22:52', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ef36cdf4-a9dd-4c92-a8ab-14d310024ab2'	System	24 Sep 2020 18:23:11
User entered 'No interference with activity (1)'	System	24 Sep 2020 18:23:11

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-24T13:22:56', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ef36cdf4-a9dd-4c92-a8ab-14d310024ab2'	System	24 Sep 2020 18:23:11
User entered 'No interference with activity (1)'	System	24 Sep 2020 18:23:11

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-24T13:23:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ef36cdf4-a9dd-4c92-a8ab-14d310024ab2' User entered 'None (0)'	System	24 Sep 2020 18:23:11
	System	24 Sep 2020 18:23:11

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:32:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-24T13:23:02', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ef36cdf4-a9dd-4c92-a8ab-14d310024ab2' User entered 'None (0)'	System	24 Sep 2020 18:23:11
	System	24 Sep 2020 18:23:11

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-24T13:23:04', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ef36cdf4-a9dd-4c92-a8ab-14d310024ab2' User entered 'None (0)'	System	24 Sep 2020 18:23:11
	System	24 Sep 2020 18:23:11

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-24T13:23:05', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ef36cdf4-a9dd-4c92-a8ab-14d310024ab2' User entered 'None (0)'	System	24 Sep 2020 18:23:11
	System	24 Sep 2020 18:23:11

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-24T13:23:08', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ef36cdf4-a9dd-4c92-a8ab-14d310024ab2'	System	24 Sep 2020 18:23:11
User entered 'No (N)'	System	24 Sep 2020 18:23:11



**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-24T13:23:09', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ef36cdf4-a9dd-4c92-a8ab-14d310024ab2'	System	24 Sep 2020 18:23:11
User entered '24 Sep 2020 13:23'	System	24 Sep 2020 18:23:11

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 14:19:00

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:32:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 4'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-25T15:15:29', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'd05b0228-4c81-4895-bdd6-247c1242720b' User entered 'None (0)'	System	25 Sep 2020 20:15:42
	System	25 Sep 2020 20:15:42

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-25T15:15:31', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'd05b0228-4c81-4895-bdd6-247c1242720b' User entered 'None (0)'	System	25 Sep 2020 20:15:42
	System	25 Sep 2020 20:15:42

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-25T15:15:32', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'd05b0228-4c81-4895-bdd6-247c1242720b' User entered 'None (0)'	System	25 Sep 2020 20:15:42
	System	25 Sep 2020 20:15:42

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:32:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-25T15:15:33', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'd05b0228-4c81-4895-bdd6-247c1242720b' User entered 'None (0)'	System	25 Sep 2020 20:15:42
	System	25 Sep 2020 20:15:42



**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-25T15:15:35', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'd05b0228-4c81-4895-bdd6-247c1242720b' User entered 'None (0)'	System	25 Sep 2020 20:15:42
	System	25 Sep 2020 20:15:42

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-25T15:15:36', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'd05b0228-4c81-4895-bdd6-247c1242720b' User entered 'None (0)'	System	25 Sep 2020 20:15:42
	System	25 Sep 2020 20:15:42

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-25T15:15:38', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'd05b0228-4c81-4895-bdd6-247c1242720b' User entered 'No (N)'	System	25 Sep 2020 20:15:42
	System	25 Sep 2020 20:15:42

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-25T15:15:39', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'd05b0228-4c81-4895-bdd6-247c1242720b' User entered '25 Sep 2020 15:15'	System	25 Sep 2020 20:15:42
	System	25 Sep 2020 20:15:42

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 5'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-26T21:26:41', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '570b70bd-92e8-4f25-8147-50bee39563b8' User entered 'None (0)'	System	27 Sep 2020 02:26:55
	System	27 Sep 2020 02:26:55



**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-26T21:26:43', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '570b70bd-92e8-4f25-8147-50bee39563b8' User entered 'None (0)'	System	27 Sep 2020 02:26:55
	System	27 Sep 2020 02:26:55

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-26T21:26:45', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '570b70bd-92e8-4f25-8147-50bee39563b8' User entered 'None (0)'	System	27 Sep 2020 02:26:55
	System	27 Sep 2020 02:26:55

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-26T21:26:46', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '570b70bd-92e8-4f25-8147-50bee39563b8' User entered 'None (0)'	System	27 Sep 2020 02:26:55
	System	27 Sep 2020 02:26:55

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-26T21:26:47', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '570b70bd-92e8-4f25-8147-50bee39563b8' User entered 'None (0)'	System	27 Sep 2020 02:26:55
	System	27 Sep 2020 02:26:55

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-26T21:26:49', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '570b70bd-92e8-4f25-8147-50bee39563b8' User entered 'None (0)'	System	27 Sep 2020 02:26:55
	System	27 Sep 2020 02:26:55

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-26T21:26:51', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '570b70bd-92e8-4f25-8147-50bee39563b8' User entered 'No (N)'	System	27 Sep 2020 02:26:55
	System	27 Sep 2020 02:26:55

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-26T21:26:52', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '570b70bd-92e8-4f25-8147-50bee39563b8' User entered '26 Sep 2020 21:26'	System	27 Sep 2020 02:26:55
	System	27 Sep 2020 02:26:55

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 14:19:00



**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 6'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-27T15:49:11', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '23bbce07-46ee-4079-b1d3-a8e99f0093f6' User entered 'None (0)'	System	27 Sep 2020 20:49:26
	System	27 Sep 2020 20:49:26

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-27T15:49:12', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '23bbce07-46ee-4079-b1d3-a8e99f0093f6' User entered 'None (0)'	System	27 Sep 2020 20:49:26
	System	27 Sep 2020 20:49:26

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-27T15:49:14', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '23bbce07-46ee-4079-b1d3-a8e99f0093f6' User entered 'None (0)'	System	27 Sep 2020 20:49:26
	System	27 Sep 2020 20:49:26

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:32:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-27T15:49:15', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '23bbce07-46ee-4079-b1d3-a8e99f0093f6' User entered 'None (0)'	System	27 Sep 2020 20:49:26
	System	27 Sep 2020 20:49:26

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-27T15:49:17', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '23bbce07-46ee-4079-b1d3-a8e99f0093f6' User entered 'None (0)'	System	27 Sep 2020 20:49:26
	System	27 Sep 2020 20:49:26

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-27T15:49:18', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '23bbce07-46ee-4079-b1d3-a8e99f0093f6' User entered 'None (0)'	System	27 Sep 2020 20:49:26
	System	27 Sep 2020 20:49:26



US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-27T15:49:21', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '23bbce07-46ee-4079-b1d3-a8e99f0093f6' User entered 'No (N)'	System	27 Sep 2020 20:49:26
	System	27 Sep 2020 20:49:26

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-27T15:49:25', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '23bbce07-46ee-4079-b1d3-a8e99f0093f6' User entered '27 Sep 2020 15:49'	System	27 Sep 2020 20:49:26
	System	27 Sep 2020 20:49:26

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	22 Sep 2020 14:19:00
User entered 'Day 7'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-28T15:49:06', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '17e84af9-214f-42ca-9d8d-c34ba428e99d' User entered 'None (0)'	System	28 Sep 2020 20:49:20
	System	28 Sep 2020 20:49:20

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-28T15:49:07', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '17e84af9-214f-42ca-9d8d-c34ba428e99d' User entered 'None (0)'	System	28 Sep 2020 20:49:20
	System	28 Sep 2020 20:49:20

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:32:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-28T15:49:09', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '17e84af9-214f-42ca-9d8d-c34ba428e99d' User entered 'None (0)'	System	28 Sep 2020 20:49:20
	System	28 Sep 2020 20:49:20



US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:32:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-28T15:49:11', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '17e84af9-214f-42ca-9d8d-c34ba428e99d' User entered 'None (0)'	System	28 Sep 2020 20:49:20
	System	28 Sep 2020 20:49:20

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-28T15:49:12', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '17e84af9-214f-42ca-9d8d-c34ba428e99d' User entered 'None (0)'	System	28 Sep 2020 20:49:20
	System	28 Sep 2020 20:49:20

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-28T15:49:14', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '17e84af9-214f-42ca-9d8d-c34ba428e99d' User entered 'None (0)'	System	28 Sep 2020 20:49:20
	System	28 Sep 2020 20:49:20

US3422101

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-28T15:49:17', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '17e84af9-214f-42ca-9d8d-c34ba428e99d' User entered 'No (N)'	System	28 Sep 2020 20:49:20
	System	28 Sep 2020 20:49:20

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-09-28T15:49:18', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '17e84af9-214f-42ca-9d8d-c34ba428e99d' User entered '28 Sep 2020 15:49'	System	28 Sep 2020 20:49:20
	System	28 Sep 2020 20:49:20

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:32:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 14:19:00

**US3422101**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:28:53



**US3422101**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:28:53

**US3422101**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:28:53

**US3422101**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 19:28:53

**US3422101**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 19:29:00

**US3422101**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'I'	System	29 Sep 2020 19:29:00

**US3422101**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 20:56:27

**US3422101**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:56:27

**US3422101**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:56:27



**US3422101**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 20:56:27

**US3422101**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:56:33

**US3422101**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'I'	System	06 Oct 2020 20:56:33

**US3422101**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:37:53

**US3422101**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:37:53

**US3422101**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:37:53

**US3422101**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 19:37:53

**US3422101**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 19:38:01



**US3422101**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'I'	System	13 Oct 2020 19:38:01

**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	16 Oct 2020 18:12:02

US3422101

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:32:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 07:43:48
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Confirmed that this is out of window. Protocol deviation completed. ' (Site from System).	Cindy Trimmer (b) (4) (b) (4)	16 Oct 2020 18:12:54
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	16 Oct 2020 18:12:02
User entered '16 Oct 2020'	Cindy Trimmer (b) (4) (b) (4)	16 Oct 2020 18:12:02

**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Clinic (Clinic)'	Cindy Trimmer (b) (4)	16 Oct 2020 18:12:02

**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'VISIT3'	System	16 Oct 2020 18:12:02

**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:32
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	16 Oct 2020 18:16:23

**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:32
User entered '16 Oct 2020'	Cindy Trimmer (b) (4)	16 Oct 2020 18:16:23

**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:32
User entered '9:15'	Cindy Trimmer (b) (4)	16 Oct 2020 18:16:23



**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered '16 Oct 2020 9:15'	System	16 Oct 2020 18:16:23

US3422101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:32
User entered '98.4' F	Cindy Trimmer (b) (4)	16 Oct 2020 18:16:23

US3422101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:32
User entered 'Oral (Oral)'	Cindy Trimmer (b) (4)	16 Oct 2020 18:16:23

**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:32
User entered empty.	Cindy Trimmer (b) (4)	16 Oct 2020 18:16:23

**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:32
User entered '75'	Cindy Trimmer (b) (4)	16 Oct 2020 18:16:23

**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'bpm'	System	16 Oct 2020 18:16:23

US3422101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:32
User entered '16'	Cindy Trimmer (b) (4)	16 Oct 2020 18:16:23

US3422101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'breaths/min'	System	16 Oct 2020 18:16:23



US3422101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:32
User entered '110'	Cindy Trimmer (b) (4)	16 Oct 2020 18:16:23

**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'mmHg'	System	16 Oct 2020 18:16:23

US3422101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:32
User entered '83'	Cindy Trimmer (b) (4)	16 Oct 2020 18:16:23

**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'mmHg'	System	16 Oct 2020 18:16:23

US3422101

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12

**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12

**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:32:16**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'No (N)'	Cindy Trimmer (b) (4)	16 Oct 2020 18:16:32

**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:32:16**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered empty.	Cindy Trimmer (b) (4)	16 Oct 2020 18:16:32



US3422101

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	16 Oct 2020 18:16:52

**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:32:16**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '16 Oct 2020'	Cindy Trimmer (b) (4)	16 Oct 2020 18:16:52

**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:32:16**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered '9:31'	Cindy Trimmer (b) (4)	16 Oct 2020 18:16:52

**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered '16 Oct 2020 9:31'	System	16 Oct 2020 18:16:52

**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	19 Feb 2021 19:57:01
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	16 Oct 2020 18:16:58

**US3422101**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'I'	System	16 Oct 2020 18:16:58

**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 64'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-10-25T18:17:49', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '1ec5611b-d528-4060-b114-728fdbf5b0e5' User entered 'No (N)'	System	25 Oct 2020 23:18:02
	System	25 Oct 2020 23:18:02



**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Have you been exposed to someone with 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)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-10-25T18:17:55', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '1ec5611b-d528-4060-b114-728fdbf5b0e5'	System	25 Oct 2020 23:18:02
User entered 'No (N)'	System	25 Oct 2020 23:18:02

**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-10-25T18:17:58', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '1ec5611b-d528-4060-b114-728fdbf5b0e5' User entered '25 Oct 2020 18:17:58'	System	25 Oct 2020 23:18:02
	System	25 Oct 2020 23:18:02

**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered '25 Oct 2020 00:01'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered '29 Oct 2020 23:59'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 71'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-11-01T04:50:50', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'eef1527e-941f-4158-9541-8fff63d24469' User entered 'No (N)'	System	01 Nov 2020 10:51:54
	System	01 Nov 2020 10:51:54

**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Have you been exposed to someone with 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)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-11-01T04:50:56', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'eef1527e-941f-4158-9541-8fff63d24469' User entered 'Yes (Y)'	System	01 Nov 2020 10:51:54
	System	01 Nov 2020 10:51:54

**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Please 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)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-11-01T04:51:16', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'eef1527e-941f-4158-9541-8fff63d24469'	System	01 Nov 2020 10:51:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Nov 2020 10:51:54



**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-11-01T04:51:45', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'eef1527e-941f-4158-9541-8fff63d24469' User entered '01 Nov 2020 04:51:45'	System	01 Nov 2020 10:51:54
	System	01 Nov 2020 10:51:54

**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered '01 Nov 2020 00:01'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered '05 Nov 2020 23:59'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered 'Day 78'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-11-08T11:41:12', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ad75cba1-7343-475c-a7d6-584e3a12c715'	System	08 Nov 2020 17:41:29
User entered 'Yes (Y)'	System	08 Nov 2020 17:41:29

US3422101

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:16

Have you been exposed to someone with 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)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-11-08T11:41:15', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ad75cba1-7343-475c-a7d6-584e3a12c715'	System	08 Nov 2020 17:41:29
User entered 'No (N)'	System	08 Nov 2020 17:41:29

**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-11-08T11:41:18', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ad75cba1-7343-475c-a7d6-584e3a12c715'	System	08 Nov 2020 17:41:29
User entered 'No (N)'	System	08 Nov 2020 17:41:29

**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-11-08T11:41:24', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ad75cba1-7343-475c-a7d6-584e3a12c715'	System	08 Nov 2020 17:41:29
User entered 'No (N)'	System	08 Nov 2020 17:41:29



**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-11-08T11:41:26', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ad75cba1-7343-475c-a7d6-584e3a12c715' User entered '08 Nov 2020 11:41:26'	System	08 Nov 2020 17:41:29
	System	08 Nov 2020 17:41:29

**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered '08 Nov 2020 00:01'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:51:37
Data entry locked.	System	25 Aug 2020 14:55:14
User entered '12 Nov 2020 23:59'	System	25 Aug 2020 14:55:14

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-11-22T09:50:45', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '5835a36c-8b2f-4c6d-80e6-f30eb3f39c13'	System	22 Nov 2020 15:50:59
User entered 'No (N)'	System	22 Nov 2020 15:50:59

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-11-22T09:50:53', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '5835a36c-8b2f-4c6d-80e6-f30eb3f39c13'	System	22 Nov 2020 15:50:59
User entered 'No (N)'	System	22 Nov 2020 15:50:59

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-11-22T09:50:56', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '5835a36c-8b2f-4c6d-80e6-f30eb3f39c13'	System	22 Nov 2020 15:50:59
User entered '22 Nov 2020 09:50:56'	System	22 Nov 2020 15:50:59

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-11-26T11:06:32', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '6f50fbce-8a52-4231-b451-daa0a1422af' User entered 'No (N)'	System	26 Nov 2020 17:06:41
	System	26 Nov 2020 17:06:41

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-11-26T11:06:35', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '6f50fbce-8a52-4231-b451-daa0a1422af'	System	26 Nov 2020 17:06:41
User entered 'No (N)'	System	26 Nov 2020 17:06:41

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-11-26T11:06:37', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '6f50fbce-8a52-4231-b451-daa0a1422af' User entered '26 Nov 2020 11:06:37'	System	26 Nov 2020 17:06:41
	System	26 Nov 2020 17:06:41

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-12-03T13:54:30', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '85b3ad39-daa1-4545-bb68-c92532233a0e' User entered 'No (N)'	System	03 Dec 2020 19:54:56
	System	03 Dec 2020 19:54:56

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-12-03T13:54:33', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '85b3ad39-daa1-4545-bb68-c92532233a0e' User entered 'No (N)'	System	03 Dec 2020 19:54:56
	System	03 Dec 2020 19:54:56

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-12-03T13:54:35', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '85b3ad39-daa1-4545-bb68-c92532233a0e' User entered '03 Dec 2020 13:54:35'	System	03 Dec 2020 19:54:56
	System	03 Dec 2020 19:54:56

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-12-10T13:15:11', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a25c9ab7-4f39-4e84-81ec-5a618bd7f95d' User entered 'No (N)'	System	10 Dec 2020 19:15:19
	System	10 Dec 2020 19:15:19

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-12-10T13:15:14', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a25c9ab7-4f39-4e84-81ec-5a618bd7f95d'	System	10 Dec 2020 19:15:19
User entered 'No (N)'	System	10 Dec 2020 19:15:19



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-12-10T13:15:15', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a25c9ab7-4f39-4e84-81ec-5a618bd7f95d' User entered '10 Dec 2020 13:15:15'	System	10 Dec 2020 19:15:19
	System	10 Dec 2020 19:15:19

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-12-18T06:52:17', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a89b122d-7f51-41fa-b610-b12f89c6ca43'	System	18 Dec 2020 12:52:24
User entered 'No (N)'	System	18 Dec 2020 12:52:24

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-12-18T06:52:19', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a89b122d-7f51-41fa-b610-b12f89c6ca43'	System	18 Dec 2020 12:52:24
User entered 'No (N)'	System	18 Dec 2020 12:52:24

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-12-18T06:52:21', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a89b122d-7f51-41fa-b610-b12f89c6ca43' User entered '18 Dec 2020 06:52:21'	System	18 Dec 2020 12:52:24
	System	18 Dec 2020 12:52:24

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-12-25T04:52:28', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '3c420800-89ed-496d-a9e0-c51d33ec215a' User entered 'No (N)'	System	25 Dec 2020 11:52:37
	System	25 Dec 2020 11:52:37

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-12-25T04:52:32', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '3c420800-89ed-496d-a9e0-c51d33ec215a' User entered 'No (N)'	System	25 Dec 2020 11:52:37
	System	25 Dec 2020 11:52:37

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-12-25T04:52:34', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '3c420800-89ed-496d-a9e0-c51d33ec215a' User entered '25 Dec 2020 04:52:34'	System	25 Dec 2020 11:52:37
	System	25 Dec 2020 11:52:37

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-12-31T09:46:35', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'b7528ae9-e17c-4679-8c25-233e21978826' User entered 'No (N)'	System	31 Dec 2020 15:46:46
	System	31 Dec 2020 15:46:46

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-12-31T09:46:40', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'b7528ae9-e17c-4679-8c25-233e21978826' User entered 'No (N)'	System	31 Dec 2020 15:46:46
	System	31 Dec 2020 15:46:46

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2020-12-31T09:46:42', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'b7528ae9-e17c-4679-8c25-233e21978826' User entered '31 Dec 2020 09:46:42'	System	31 Dec 2020 15:46:46
	System	31 Dec 2020 15:46:46

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-01-08T09:11:47', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'f0ca910b-909f-41b7-9e94-3ff15d7f1c3f' User entered 'No (N)'	System	08 Jan 2021 15:12:13
	System	08 Jan 2021 15:12:13

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-01-08T09:11:56', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'f0ca910b-909f-41b7-9e94-3ff15d7f1c3f'	System	08 Jan 2021 15:12:13
User entered 'No (N)'	System	08 Jan 2021 15:12:13



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-01-08T09:12:08', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'f0ca910b-909f-41b7-9e94-3ff15d7f1c3f' User entered '08 Jan 2021 09:12:08'	System	08 Jan 2021 15:12:13
	System	08 Jan 2021 15:12:13

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-01-14T13:51:01', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '35d5f92b-a463-4198-91ef-487a89815635'	System	14 Jan 2021 20:05:37
User entered 'No (N)'	System	14 Jan 2021 20:05:37

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-01-14T14:05:28', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '35d5f92b-a463-4198-91ef-487a89815635'	System	14 Jan 2021 20:05:37
User entered 'No (N)'	System	14 Jan 2021 20:05:37

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-01-14T14:05:31', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '35d5f92b-a463-4198-91ef-487a89815635' User entered '14 Jan 2021 14:05:31'	System	14 Jan 2021 20:05:37
	System	14 Jan 2021 20:05:37

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-01-22T19:32:54', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '15feea2d-2bc6-47ed-88fc-b4bef4d25806'	System	23 Jan 2021 01:32:59
User entered 'No (N)'	System	23 Jan 2021 01:32:59

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-01-22T19:32:56', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '15feea2d-2bc6-47ed-88fc-b4bef4d25806'	System	23 Jan 2021 01:32:59
User entered 'No (N)'	System	23 Jan 2021 01:32:59

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-01-22T19:32:57', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '15feea2d-2bc6-47ed-88fc-b4bef4d25806' User entered '22 Jan 2021 19:32:57'	System	23 Jan 2021 01:32:59

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-01-30T10:06:38', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '49d8705c-99c8-4949-9560-ca8238906b4a'	System	30 Jan 2021 16:06:45
User entered 'No (N)'	System	30 Jan 2021 16:06:45

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-01-30T10:06:39', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '49d8705c-99c8-4949-9560-ca8238906b4a'	System	30 Jan 2021 16:06:45
User entered 'No (N)'	System	30 Jan 2021 16:06:45

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-01-30T10:06:41', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '49d8705c-99c8-4949-9560-ca8238906b4a' User entered '30 Jan 2021 10:06:41'	System	30 Jan 2021 16:06:45
	System	30 Jan 2021 16:06:45

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-02-04T08:17:39', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '17b2c341-0555-4967-9030-abd2c4d91915'	System	04 Feb 2021 14:17:50
User entered 'No (N)'	System	04 Feb 2021 14:17:50

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-02-04T08:17:45', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '17b2c341-0555-4967-9030-abd2c4d91915'	System	04 Feb 2021 14:17:50
User entered 'No (N)'	System	04 Feb 2021 14:17:50



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-02-04T08:17:47', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '17b2c341-0555-4967-9030-abd2c4d91915'	System	04 Feb 2021 14:17:50
User entered '04 Feb 2021 08:17:47'	System	04 Feb 2021 14:17:50

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-02-11T10:18:37', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '39d4b07c-6f63-44ce-ab1c-556ca96a8679' User entered 'No (N)'	System	11 Feb 2021 16:18:48
	System	11 Feb 2021 16:18:48

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-02-11T10:18:41', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '39d4b07c-6f63-44ce-ab1c-556ca96a8679' User entered 'No (N)'	System	11 Feb 2021 16:18:48

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-02-11T10:18:43', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '39d4b07c-6f63-44ce-ab1c-556ca96a8679' User entered '11 Feb 2021 10:18:43'	System	11 Feb 2021 16:18:48
	System	11 Feb 2021 16:18:48

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-02-18T11:51:09', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'e37413b2-a6a6-4449-ad2b-c750e3379b2f' User entered 'No (N)'	System	18 Feb 2021 17:51:19
	System	18 Feb 2021 17:51:19

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-02-18T11:51:12', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'e37413b2-a6a6-4449-ad2b-c750e3379b2f' User entered 'No (N)'	System	18 Feb 2021 17:51:19
	System	18 Feb 2021 17:51:19

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-02-18T11:51:16', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'e37413b2-a6a6-4449-ad2b-c750e3379b2f' User entered '18 Feb 2021 11:51:16'	System	18 Feb 2021 17:51:19
	System	18 Feb 2021 17:51:19

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-02-25T20:29:33-06:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a9bb4a83-350a-4abe-894e-9275d3a8ed2f'	System	26 Feb 2021 02:38:11
User entered 'No (N)'	System	26 Feb 2021 02:38:11

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-02-25T20:29:36-06:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a9bb4a83-350a-4abe-894e-9275d3a8ed2f' User entered 'No (N)'	System	26 Feb 2021 02:38:11

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-02-25T20:29:39-06:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a9bb4a83-350a-4abe-894e-9275d3a8ed2f' User entered '26 Feb 2021 02:29:39'	System	26 Feb 2021 02:38:11
	System	26 Feb 2021 02:38:11

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-03-04T06:54:57-06:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '82c70d3d-2c34-436a-b144-37ba82ac6eeb'	System	04 Mar 2021 12:55:08
User entered 'No (N)'	System	04 Mar 2021 12:55:08

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-03-04T06:55:00-06:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '82c70d3d-2c34-436a-b144-37ba82ac6eeb'	System	04 Mar 2021 12:55:08
User entered 'No (N)'	System	04 Mar 2021 12:55:08



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-03-04T06:55:03-06:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '82c70d3d-2c34-436a-b144-37ba82ac6eeb' User entered '04 Mar 2021 06:55:03'	System	04 Mar 2021 12:55:08
	System	04 Mar 2021 12:55:08

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-03-12T14:16:33-06:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '53f1450b-4227-490c-9ca5-045dd8afb1b'	System	12 Mar 2021 20:16:39
User entered 'No (N)'	System	12 Mar 2021 20:16:39

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-03-12T14:16:35-06:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '53f1450b-4227-490c-9ca5-045dd8afb1b'	System	12 Mar 2021 20:16:39
User entered 'No (N)'	System	12 Mar 2021 20:16:39

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-03-12T14:16:38-06:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '53f1450b-4227-490c-9ca5-045dd8afb1b' User entered '12 Mar 2021 14:16:38'	System	12 Mar 2021 20:16:39
	System	12 Mar 2021 20:16:39

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-03-20T12:01:46-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'f6f5deb5-68d4-42e1-ae62-5116dbb11c66'	System	20 Mar 2021 17:03:38
User entered 'No (N)'	System	20 Mar 2021 17:03:38

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-03-20T12:01:48-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'f6f5deb5-68d4-42e1-ae62-5116dbb11c66'	System	20 Mar 2021 17:03:38
User entered 'No (N)'	System	20 Mar 2021 17:03:38

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-03-20T12:01:50-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'f6f5deb5-68d4-42e1-ae62-5116dbb11c66'	System	20 Mar 2021 17:03:38
User entered '20 Mar 2021 12:01:50'	System	20 Mar 2021 17:03:38

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-03-29T09:46:32-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a6377529-db53-4033-8c8c-930dd5687fa5'	System	29 Mar 2021 14:46:58
User entered 'No (N)'	System	29 Mar 2021 14:46:58

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-03-29T09:46:37-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a6377529-db53-4033-8c8c-930dd5687fa5'	System	29 Mar 2021 14:46:58
User entered 'No (N)'	System	29 Mar 2021 14:46:58

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-03-29T09:46:39-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'a6377529-db53-4033-8c8c-930dd5687fa5'	System	29 Mar 2021 14:46:58
User entered '29 Mar 2021 09:46:39'	System	29 Mar 2021 14:46:58

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-04-01T16:36:56-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ae9a47cd-cf64-4ccf-b111-ee826cd9126c' User entered 'No (N)'	System	01 Apr 2021 21:37:03
	System	01 Apr 2021 21:37:03

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-04-01T16:36:58-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ae9a47cd-cf64-4ccf-b111-ee826cd9126c' User entered 'No (N)'	System	01 Apr 2021 21:37:03
	System	01 Apr 2021 21:37:03



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-04-01T16:37:00-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'ae9a47cd-cf64-4ccf-b111-ee826cd9126c' User entered '01 Apr 2021 16:37:00'	System	01 Apr 2021 21:37:03
	System	01 Apr 2021 21:37:03

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-04-08T06:55:36-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'bb0aabd5-bd21-44da-917b-89b96ad478bf'	System	08 Apr 2021 11:55:52
User entered 'No (N)'	System	08 Apr 2021 11:55:52

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-04-08T06:55:44-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'bb0aabd5-bd21-44da-917b-89b96ad478bf'	System	08 Apr 2021 11:55:52
User entered 'No (N)'	System	08 Apr 2021 11:55:52

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-04-08T06:55:49-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'bb0aabd5-bd21-44da-917b-89b96ad478bf' User entered '08 Apr 2021 06:55:49'	System	08 Apr 2021 11:55:52
	System	08 Apr 2021 11:55:52

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-04-15T09:14:09-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '9965d24d-11e4-4743-81a8-ee602ce2e2a7'	System	15 Apr 2021 14:18:04
User entered 'Yes (Y)'	System	15 Apr 2021 14:18:04

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-04-15T09:15:56-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '9965d24d-11e4-4743-81a8-ee602ce2e2a7'	System	15 Apr 2021 14:18:04
User entered 'No (N)'	System	15 Apr 2021 14:18:04

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-04-15T09:15:21-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '9965d24d-11e4-4743-81a8-ee602ce2e2a7'	System	15 Apr 2021 14:18:04
User entered 'No (N)'	System	15 Apr 2021 14:18:04

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-04-15T09:15:19-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '9965d24d-11e4-4743-81a8-ee602ce2e2a7'	System	15 Apr 2021 14:18:04
User entered 'Yes (Y)'	System	15 Apr 2021 14:18:04

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Please 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 (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-04-15T09:16:24-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '9965d24d-11e4-4743-81a8-ee602ce2e2a7'	System	15 Apr 2021 14:18:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Apr 2021 14:18:04

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-04-15T09:17:53-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '9965d24d-11e4-4743-81a8-ee602ce2e2a7'	System	15 Apr 2021 14:18:04
User entered '15 Apr 2021 09:17:53'	System	15 Apr 2021 14:18:04



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-04-22T06:48:14-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '161304dd-f340-4ab9-afb9-569cb74dc7c7'	System	22 Apr 2021 11:48:24
User entered 'No (N)'	System	22 Apr 2021 11:48:24

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-04-22T06:48:16-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '161304dd-f340-4ab9-afb9-569cb74dc7c7'	System	22 Apr 2021 11:48:24
User entered 'No (N)'	System	22 Apr 2021 11:48:24

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-04-22T06:48:18-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '161304dd-f340-4ab9-afb9-569cb74dc7c7'	System	22 Apr 2021 11:48:24
User entered '22 Apr 2021 06:48:18'	System	22 Apr 2021 11:48:24

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[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 (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-04-30T09:14:57-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '7b2313e6-810f-4912-8e31-4d50cf0454a6'	System	30 Apr 2021 14:15:05
User entered 'No (N)'	System	30 Apr 2021 14:15:05

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

Have you been exposed to someone with 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 (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-04-30T09:15:00-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '7b2313e6-810f-4912-8e31-4d50cf0454a6'	System	30 Apr 2021 14:15:05
User entered 'No (N)'	System	30 Apr 2021 14:15:05

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (022FD28F-A814-4F32-AAE0-1104CDF9594C)', Time: '2021-04-30T09:15:02-05:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: '7b2313e6-810f-4912-8e31-4d50cf0454a6'	System	30 Apr 2021 14:15:05
User entered '30 Apr 2021 09:15:02'	System	30 Apr 2021 14:15:05

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:18:36



**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 02:18:36

**US3422101**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:32:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:18:36
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 02:18:36



US3422101

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:32:16

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 02:32:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-03-01T17:15:46-06:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'b3baa085-8549-4eb7-acaf-35154d61222c'	System	01 Mar 2021 23:18:13
User entered 'No (N)'	System	01 Mar 2021 23:18:13

**US3422101**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 02:32:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1CE04354-1494-4A99-9FCF-D99F54D25242)', Time: '2021-03-01T17:15:48-06:00', User OID: 'PatientReportedOutcome (US3422101)', ODM File OID: 'b3baa085-8549-4eb7-acaf-35154d61222c' User entered '01 Mar 2021 17:15:48'	System	01 Mar 2021 23:18:13
	System	01 Mar 2021 23:18:13

**US3422101**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 18:48:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 18:35:35

US3422101

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 18:48:28
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 12-NOV-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 12-NOV-2020 is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 12:27:21
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 12-NOV-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 12-NOV-2020 is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate.' answered with 'THIS IS SAFETY CALL FORM.' (Site from DM).	April Hanlotxomphou (b) (4)	19 Nov 2020 15:32:08
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 12-NOV-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 12-NOV-2020 is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:12:18
User entered '17 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 18:35:35

**US3422101**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 18:48:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:35:35

**US3422101**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 18:48:28
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:35:35

**US3422101**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User signature succeeded.	Clarence Creech (b) (4)	05 Mar 2021 18:48:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 18:35:20

**US3422101**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:39:12
User entered 'I'	System	17 Nov 2020 18:35:20



**US3422101**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:54:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	18 Dec 2020 17:06:15

**US3422101**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:54:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '18 Dec 2020'	Cindy Trimmer (b) (4)	18 Dec 2020 17:06:15

**US3422101**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:54:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	18 Dec 2020 17:06:15

**US3422101**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:54:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	Cindy Trimmer (b) (4)	18 Dec 2020 17:06:15

**US3422101**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:54:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	18 Dec 2020 17:06:04

**US3422101**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:54:38
User entered 'I'	System	18 Dec 2020 17:06:04

**US3422101**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:54:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 17:39:02

**US3422101**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:54:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:39:02



**US3422101**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:54:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:39:02

**US3422101**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:54:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 17:39:02

**US3422101**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:54:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 17:39:09

**US3422101**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:54:38
User entered 'I'	System	20 Jan 2021 17:39:09

**US3422101**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:54:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 17:59:24

**US3422101**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:54:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:59:24

**US3422101**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:54:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:59:24

**US3422101**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:54:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:59:24



**US3422101**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:54:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 17:59:13

**US3422101**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:54:38
User entered 'I'	System	22 Feb 2021 17:59:13

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:18:27

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:18:27

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:18:27

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered 'VISIT4'	System	25 Mar 2021 17:18:27

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'No (N)'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	30 Mar 2021 14:43:35

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	(b) (4) Cindy Trimmer (b) (4) (b) (4)	30 Mar 2021 14:43:35



**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	(b) (4) Cindy Trimmer (b) (4) (b) (4)	30 Mar 2021 14:43:35

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered empty.	System	30 Mar 2021 14:43:35

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	(b) (4) Cindy Trimmer (b) (4) (b) (4)	30 Mar 2021 14:43:35

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	Cindy Trimmer (b) (4)	30 Mar 2021 14:43:35

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	30 Mar 2021 14:43:35

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	Cindy Trimmer (b) (4)	30 Mar 2021 14:43:35

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered empty.	System	30 Mar 2021 14:43:35

US3422101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	(b) (4) Cindy Trimmer (b) (4) (b) (4)	30 Mar 2021 14:43:35



**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered empty.	System	30 Mar 2021 14:43:35

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	(b) (4) Cindy Trimmer (b) (4) (b) (4)	30 Mar 2021 14:43:35

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered empty.	System	30 Mar 2021 14:43:35

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	(b) (4) Cindy Trimmer (b) (4) (b) (4)	30 Mar 2021 14:43:35

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered empty.	System	30 Mar 2021 14:43:35

US3422101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18

US3422101

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:32:16**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:18:44



**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:32:16**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:18:44

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:32:16**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:19:02

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:32:16**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:19:02

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '09:40'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:19:02

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered '25 Mar 2021 09:40'	System	25 Mar 2021 17:19:02

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:19:38

**US3422101**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:14:18
User entered 'I'	System	25 Mar 2021 17:19:38

**US3422101**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
	(b) (4)	
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	20 Apr 2021 17:42:37
	(b) (4)	



**US3422101**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
	(b) (4)	
User entered '20 Apr 2021'	Cindy Trimmer (b) (4)	20 Apr 2021 17:42:37
	(b) (4)	

**US3422101**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cindy Trimmer (b) (4) (b) (4)	20 Apr 2021 17:42:37

**US3422101**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:32:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
	(b) (4)	
User entered empty.	Cindy Trimmer (b) (4)	20 Apr 2021 17:42:37
	(b) (4)	

**US3422101**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
	(b) (4)	
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	20 Apr 2021 17:43:02
	(b) (4)	

**US3422101**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:32:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 17:43:02

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:32:16**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:35
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:10:11

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:32:16**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:35
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '08:00'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:10:11

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:32:16**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:35
User entered '11 Nov 2020 08:00'	System	18 Nov 2020 21:10:11



**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:32:16**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:35
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:10:11

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:32:16**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:35
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:10:11

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:32:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:13:49

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:13:49

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 21:13:49

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:32:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '099'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:13:49

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:32:16**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User entered '%'	System	18 Nov 2020 21:13:49

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '099.2' F	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:13:49



US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:32:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:13:49

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:32:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:13:49

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:32:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:13:49

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:32:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	19 Nov 2020 14:52:40
User entered empty.	Cindy Trimmer (b) (4)	18 Nov 2020 21:13:49
	(b) (4), (b) (6)	

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:32:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:13:49

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:13:49

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:32:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:13:49

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:32:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Severe (Severe)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:13:49



US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:32:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:13:49

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:32:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:13:49

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:32:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:13:49

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:32:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:13:49

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:13:49

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:13:49

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:32:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:13:49

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:32:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:13:49



US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:32:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:16:02

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:32:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:16:02

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:32:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:16:02

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 17:32:16**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '099'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:16:02

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 17:32:16**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User entered '%'	System	18 Nov 2020 21:16:02

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:32:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '098.9' F	(b) (4), (b) (6)	18 Nov 2020 21:16:02

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:32:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:16:02

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:32:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:16:02



US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:32:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:16:02

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:32:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:16:02

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:32:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:16:02

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:32:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:16:02

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 21:16:02

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	18 Nov 2020 21:16:02

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:32:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:16:02

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 17:32:16**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:16:02



**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:16:02

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:32:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:16:02

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:16:02

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:16:02

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:32:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:16:02

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:32:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:16:02

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:32:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47



**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 21:17:47

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:32:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '100'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:32:16**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User entered '%'	System	18 Nov 2020 21:17:47

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:32:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '098.1' F	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:32:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:32:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:32:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:32:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47



US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:32:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:32:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:32:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:32:16**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:32:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:32:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Moderate (Moderate)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:32:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47



**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:17:47

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:32:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:32:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:32:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:32:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '099'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33



**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 17:32:16**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User entered '%'	System	18 Nov 2020 21:19:33

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:32:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '098.7' F	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:32:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:32:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:32:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:32:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:32:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:32:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33



US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:32:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:32:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 17:32:16**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:32:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:32:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:32:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:32:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33



US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:32:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:32:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:19:33

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:32:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '14 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 21:21:12

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:32:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '099'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:32:16**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User entered '%'	System	18 Nov 2020 21:21:12

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '098.7' F	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12



**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:32:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:32:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:32:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:32:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:32:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:32:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12



US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:32:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:32:16**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:32:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:32:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:32:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:21:12



US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:32:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '15 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:32:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '099'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 17:32:16**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User entered '%'	System	18 Nov 2020 21:22:42

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:32:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '099.8' F	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:32:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42



US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:32:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:32:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:32:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:32:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 17:32:16**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:32:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42



**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:32:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:32:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:32:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:32:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:22:42

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:32:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15



US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:32:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:32:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '098'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:32:16**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User entered '%'	System	18 Nov 2020 21:24:15

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:32:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '098.1' F	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:32:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:32:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:32:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15



US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:32:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:32:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:32:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:32:16**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:32:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:32:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15



**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:32:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:32:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:32:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:38
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:24:15

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:32:16**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:25:10

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:32:16**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:25:10

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:32:16

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Nov 2020 15:28:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 15:28:25
User entered 'No (N)' reason for change: Data Entry Error	April Hanlotxomphou (b) (4)	19 Nov 2020 15:28:25
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 21:25:10
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 21:25:10

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:32:16**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:25:10



**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:32:16**

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	18 Nov 2020 21:25:10

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:32:16

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:25:10

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:32:16**

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:25:10

US3422101

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:32:16

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:25:10

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:32:16**

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:41
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:25:10

**US3422101**

**Folder: Covid-19 Assessment 11 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:32:16**

**COVID-19 Positive (CSA Programming Field Only)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:39:41
User entered '0'	System	19 Nov 2020 15:28:25

US3422101

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:32:16

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14NOV2020 is reported under Illness visit 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)	24 Feb 2021 10:19:28
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14NOV2020 is reported under Illness visit 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 'UPDATED' (Site from DM).	April Hanlotxomphou (b) (4)	11 Feb 2021 18:48:48
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14NOV2020 is reported under Illness visit 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 Feb 2021 06:46:57
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	18 Nov 2020 21:30:09

US3422101

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:32:16

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	April Hanlotxomphou (b) (4)	11 Feb 2021 18:48:08
User closed query 'Per CDM: A response 'Yes/No/NA (Covid-19 Negative)' is required for this field. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 16:24:23
Query 'Per CDM: A response 'Yes/No/NA (Covid-19 Negative)' is required for this field. Please update accordingly. ' answered with 'updated' (Site from DM).	Anna Gallion (b) (4)	07 Dec 2020 17:44:00
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Anna Gallion (b) (4)	07 Dec 2020 17:43:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	07 Dec 2020 03:20:53
User opened query 'Per CDM: A response 'Yes/No/NA (Covid-19 Negative)' is required for this field. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 03:20:51
Query 'Data is required. Please complete.' answered with 'not collected' (Site from System).	Anna Gallion (b) (4)	02 Dec 2020 19:53:48
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 19:53:26
User entered empty; reason for change Data Entry Error	Anna Gallion (b) (4)	02 Dec 2020 19:53:26
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	April Hanlotxomphou (b) (4)	19 Nov 2020 15:29:30
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 21:30:09



US3422101

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:32:16

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '14 Nov 2020' reason for change: Data Entry Error	(b) (4) April Hanlotxomphou (b) (4)	11 Feb 2021 18:48:08
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14NOV2020 is reported under Illness Visits 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)	09 Dec 2020 08:20:04
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14NOV2020 is reported under Illness Visits 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 'not collected; i do not see this in ppd' (Site from DM).	Anna Gallion (b) (4) (b) (4)	02 Dec 2020 19:53:50
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14NOV2020 is reported under Illness Visits 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)	26 Nov 2020 06:59:27
User entered empty; reason for change Data Entry Error	April Hanlotxomphou (b) (4)	19 Nov 2020 15:29:30
User entered '12 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 21:30:09

**US3422101**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	18 Nov 2020 21:30:09

**US3422101**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:30:09

**US3422101**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:30:09

**US3422101**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	18 Nov 2020 21:30:09

**US3422101**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:30:09

**US3422101**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:30:09

**US3422101**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	18 Nov 2020 21:30:09



**US3422101**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:30:09

**US3422101**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:30:09

**US3422101**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	18 Nov 2020 21:30:09

**US3422101**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:30:09

**US3422101**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:30:09

**US3422101**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	18 Nov 2020 21:30:09

**US3422101**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:30:09

**US3422101**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:30:09



**US3422101**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	18 Nov 2020 21:30:09

**US3422101**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:30:09

**US3422101**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 21:30:09

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	19 Nov 2020 15:41:50

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '12 Nov 2020'	Cindy Trimmer (b) (4)	19 Nov 2020 15:41:50

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Clinic (Clinic)'	Cindy Trimmer (b) (4)	19 Nov 2020 15:41:50

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User entered 'SICKD1'	System	19 Nov 2020 15:41:50

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	19 Nov 2020 15:42:17



**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '12 Nov 2020'	Cindy Trimmer (b) (4)	19 Nov 2020 15:42:17

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '08:00'	Cindy Trimmer (b) (4)	19 Nov 2020 15:42:17

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User entered '12 Nov 2020 08:00'	System	19 Nov 2020 15:42:17

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered missing code ND - Not Done.	(b) (4) Cindy Trimmer (b) (4)	19 Nov 2020 15:42:17
DataPoint set to visible.	(b) (4) System	19 Nov 2020 15:41:50

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered missing code ND - Not Done.	(b) (4) Cindy Trimmer (b) (4)	19 Nov 2020 15:42:17
DataPoint set to visible.	(b) (4) System	19 Nov 2020 15:41:50

US3422101

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '98.1' F	Cindy Trimmer (b) (4)	19 Nov 2020 15:42:17

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Oral (Oral)'	Cindy Trimmer (b) (4)	19 Nov 2020 15:42:17

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered empty.	(b) (4) Cindy Trimmer (b) (4)	19 Nov 2020 15:42:17



**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '65'	Cindy Trimmer (b) (4)	19 Nov 2020 15:42:17

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User entered 'bpm'	System	19 Nov 2020 15:42:17

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '16'	Cindy Trimmer (b) (4)	19 Nov 2020 15:42:17

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User entered 'breaths/min'	System	19 Nov 2020 15:42:17

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '114'	Cindy Trimmer (b) (4)	19 Nov 2020 15:42:17

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User entered 'mmHg'	System	19 Nov 2020 15:42:17

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '76'	Cindy Trimmer (b) (4)	19 Nov 2020 15:42:17

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User entered 'mmHg'	System	19 Nov 2020 15:42:17



**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	02 May 2021 16:11:52

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:32:16**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:32:16**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	19 Nov 2020 15:42:36

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:32:16**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '12 Nov 2020'	Cindy Trimmer (b) (4)	19 Nov 2020 15:42:36

US3422101

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:32:16

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	19 Nov 2020 15:42:44

**US3422101**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 17:32:16**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:11:52
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '12 Nov 2020'	Cindy Trimmer (b) (4)	19 Nov 2020 15:42:44

US3422101

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

Form: Visit Date

Generated On: 09 Jun 2021 17:32:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	08 Jan 2021 20:55:28

**US3422101**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '08 Jan 2021'	Cindy Trimmer (b) (4)	08 Jan 2021 20:55:28



**US3422101**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

[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 11:36:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Clinic (Clinic)'	Cindy Trimmer (b) (4)	08 Jan 2021 20:55:28

**US3422101**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:32:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 20:55:28

**US3422101**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:32:16**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '6 Jan 2021'	Cindy Trimmer (b) (4)	08 Jan 2021 20:57:03

**US3422101**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:32:16**

[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 11:36:58
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User entered '0'	Wendy Winn (b) (4)	08 Apr 2021 19:16:19
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:28:55

**US3422101**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:32:16**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	08 Jan 2021 20:57:03

US3422101

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

Form: Unblinding

Generated On: 09 Jun 2021 17:32:16

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 11:19:14
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'field updated' (Site from DM).	Wendy Winn (b) (4)	08 Apr 2021 19:16:50
User entered 'Amendment 6 or later (Amendment 6 or later)'	Wendy Winn (b) (4)	08 Apr 2021 19:16:19
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:37:12
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:28:55

US3422101

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

Form: Unblinding

Generated On: 09 Jun 2021 17:32:16

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '08 Jan 2021'	Cindy Trimmer (b) (4)	08 Jan 2021 20:57:03

**US3422101**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:32:16**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'mRNA-1273 (mRNA-1273)'	Cindy Trimmer (b) (4)	08 Jan 2021 20:57:03



**US3422101**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:32:16**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 12:49:29
User entered 'mRNA-1273 (mRNA-1273)'	Cindy Trimmer (b) (4) (b) (4)	08 Jan 2021 20:57:03

**US3422101**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:32:16**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 12:49:29
User entered 'mRNA-1273 (mRNA-1273)'	Cindy Trimmer (b) (4)	08 Jan 2021 20:57:03
	(b) (4)	

**US3422101**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:32:16**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'No (N)'	Cindy Trimmer (b) (4)	08 Jan 2021 20:57:03

**US3422101**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:32:16**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User entered empty.	System	08 Jan 2021 20:57:03

**US3422101**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:32:16**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User entered empty.	System	08 Jan 2021 20:57:03

US3422101

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	08 Jan 2021 20:57:16

**US3422101**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:32:16**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '08 Jan 2021'	Cindy Trimmer (b) (4)	08 Jan 2021 20:57:16

**US3422101**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:32:16**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '11:50'	Cindy Trimmer (b) (4)	08 Jan 2021 20:57:16



**US3422101**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User entered '08 Jan 2021 11:50'	System	08 Jan 2021 20:57:16

**US3422101**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:32:16**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	08 Jan 2021 20:57:27

**US3422101**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:32:16**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '08 Jan 2021'	Cindy Trimmer (b) (4)	08 Jan 2021 20:57:27

**US3422101**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:32:16**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '11:53'	Cindy Trimmer (b) (4)	08 Jan 2021 20:57:27

**US3422101**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:36:58
User entered '08 Jan 2021 11:53'	System	08 Jan 2021 20:57:27

US3422101

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:32:16

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:46:18
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 7; end date: Day 10). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:03:47
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 7; end date: Day 10). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'ediary entry error. HA did not last over 7 days. ' (Site from DM).	Naomi Kown (b) (4) (b) (4)	22 Mar 2021 18:55:27
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 7; end date: Day 10). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 09:56:41
User signature succeeded.	Clarence Creech (b) (4) (b) (4)	18 Mar 2021 21:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:38:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 18:36:06

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 11:45:27

US3422101

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Streptococcal infections, PT: Pharyngitis streptococcal, LLT: Streptococcal pharyngitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:08:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:08:48
Data point term sent to Coder	System	18 Nov 2020 21:07:29
Coding entries removed.	(b) (4), (b) (6)	18 Nov 2020 21:06:47
User entered 'Streptococcal pharyngitis' reason for change: New Information	(b) (4), (b) (6)	18 Nov 2020 21:06:47
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 18:42:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 18:42:48
Data point term sent to Coder	System	17 Nov 2020 18:42:00
User entered 'DIZZINESS' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 18:41:02
Data point term sent to Coder	System	17 Nov 2020 18:40:59
User entered 'dizzines'	(b) (4), (b) (6)	17 Nov 2020 18:40:28



**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 21:06:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 21:06:47
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	18 Nov 2020 21:06:47
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 18:40:28
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User entered empty.	System	17 Nov 2020 18:40:28

US3422101

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User closed query 'Please confirm subject's AE of Streptococcal Pharyngitis is still ongoing. Otherwise, update EDC and source with the end date of event. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:56:22
Query 'Please confirm subject's AE of Streptococcal Pharyngitis is still ongoing. Otherwise, update EDC and source with the end date of event. ' answered by data change (Site from CRA).	System	19 Mar 2021 16:59:56
User entered 'No (N)' reason for change: Data Entry Error	Naomi Kown (b) (4)	19 Mar 2021 16:59:56
User opened query 'Please confirm subject's AE of Streptococcal Pharyngitis is still ongoing. Otherwise, update EDC and source with the end date of event. ' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 15:46:20
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 15:45:32
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:56:36
DataPoint Un-verified.	Naomi Kown (b) (4)	19 Mar 2021 16:59:56
User entered '26 Nov 2020' reason for change: Data Entry Error	(b) (4) Naomi Kown (b) (4)	19 Mar 2021 16:59:56
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:40:28



**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User entered empty.	System	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:40:28



**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	17 Nov 2020 18:40:28



US3422101

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:16

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User closed query 'Per CDM: AE start date is after last dose, however, Action Taken with IP is recorded as None. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 04:39:07
Query 'Per CDM: AE start date is after last dose, however, Action Taken with IP is recorded as None. Please review and update as appropriate. Thank you' answered with 'no IP action taken because NA' (Site from DM).	Anna Gallion (b) (4) (b) (4)	02 Dec 2020 19:38:04
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Anna Gallion (b) (4) (b) (4)	02 Dec 2020 19:37:45
User opened query 'Per CDM: AE start date is after last dose, however, Action Taken with IP is recorded as None. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 16:02:01
User entered 'None (NONE)'	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '0' reason for change: New Information	(b) (4), (b) (6)	18 Nov 2020 21:06:47
User entered '1'	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '1' reason for change: New Information	(b) (4), (b) (6)	18 Nov 2020 21:06:47
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 18:40:28

US3422101

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User closed query 'Please confirm subject's AE of Streptococcal Pharyngitis has not recovered. Otherwise, update EDC and source with the end date of event.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:57:00
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 16:56:51
Query 'Please confirm subject's AE of Streptococcal Pharyngitis has not recovered. Otherwise, update EDC and source with the end date of event.' answered by data change (Site from CRA).	System	19 Mar 2021 16:59:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Naomi Kown (b) (4) (b) (4)	19 Mar 2021 16:59:56
User opened query 'Please confirm subject's AE of Streptococcal Pharyngitis has not recovered. Otherwise, update EDC and source with the end date of event.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 15:47:09
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 15:46:33
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 18:40:28

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User entered '0'	System	17 Nov 2020 18:40:28



**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:45:27
User entered '1'	System	18 Nov 2020 21:06:47

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 11:45:27

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:45:24
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:42:38
User entered	System	22 Feb 2021 17:18:33
'USA-US082-2021-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	22 Feb 2021 17:18:33

US3422101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:45:24
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Gastrointestinal stenosis and obstruction NEC, PT: Ileus, LLT: Ileus - version MedDRA\\23.0.	Coder Import (b) (4)	20 Feb 2021 16:17:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Feb 2021 16:17:48
	(b) (4)	
Data point term sent to Coder	System	20 Feb 2021 16:16:46
User entered 'Ileus'	Naomi Kown (b) (4)	20 Feb 2021 16:16:00
	(b) (4)	

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered 'Yes (Y)'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered 'No (N)'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered 'No (N)'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

US3422101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '13 Feb 2021'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00



**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered empty.	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Feb 2021 16:16:00

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered 'No (N)'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '15 Feb 2021'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered empty.	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Feb 2021 16:16:00

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

US3422101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
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	20 Feb 2021 16:16:31
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	20 Feb 2021 16:16:00
User entered 'Yes (Y)'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00



**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '0'	Naomi Kown (b) (4)	20 Feb 2021 16:16:00
	(b) (4)	

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '0'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

US3422101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		20 Feb 2021 16:16:31
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		20 Feb 2021 16:16:31
User entered '1' reason for change: Data Entry Error Naomi Kown	(b) (4)	20 Feb 2021 16:16:31
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	20 Feb 2021 16:16:00
User entered '0'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '13 Feb 2021'	Naomi Kown (b) (4)	20 Feb 2021 16:16:00
	(b) (4)	

US3422101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:45:24
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.	(b) (4), (b) (6)	12 Mar 2021 14:49:25
' (Site from Safety).		
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.	Naomi Kown (b) (4)	11 Mar 2021 18:38:53
' answered with 'sent on 3/9/21' (Site from Safety).	(b) (4)	
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.	(b) (4), (b) (6)	03 Mar 2021 21:10:53
' (Site from Safety).		
User entered '15 Feb 2021'	Naomi Kown (b) (4)	20 Feb 2021 16:16:00
	(b) (4)	

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered 'No (N)'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered empty.	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '0'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00



**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '0'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '0'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

US3422101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:01:27
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product and study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 14:20:50
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product and study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'corrected' (Site from Safety).	Naomi Kown (b) (4)	19 Mar 2021 17:07:30
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	Naomi Kown (b) (4)	19 Mar 2021 17:07:07
	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:49:16
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:45:24
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product and study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 14:20:43
User closed query 'PV Query Urgent: Please provide causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 14:49:34
Query 'PV Query Urgent: Please provide causality assessment for the event as soon as possible.' answered with 'see SAE comments' (Site from Safety).	Naomi Kown (b) (4)	11 Mar 2021 20:36:26
	(b) (4)	
User opened query 'PV Query Urgent: Please provide causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 02:08:44
User entered 'Not Applicable (NOT APPLICABLE)'	Naomi Kown (b) (4)	20 Feb 2021 16:16:00
	(b) (4)	

US3422101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:33:14
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 17:16:34
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 17:16:34
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:45:24
User closed query 'PV Query Urgent: Please provide causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 14:49:36
Query 'PV Query Urgent: Please provide causality assessment for the event as soon as possible.' answered with 'see SAE comments' (Site from Safety).	Naomi Kown (b) (4) (b) (4)	11 Mar 2021 20:36:35
User opened query 'PV Query Urgent: Please provide causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 02:08:50
User entered 'Not Applicable (NOT APPLICABLE)'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

US3422101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:16

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:22:33
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 17:49:06
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 01:32:27
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:45:24
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 16:16:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Feb 2021 16:16:31
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:31
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Feb 2021 16:16:00
User entered empty.	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '0'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

US3422101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 15:12:38
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).	(b) (4), (b) (6)	12 Mar 2021 14:49:50
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 'will enter' (Site from Safety).	Naomi Kown (b) (4) (b) (4)	11 Mar 2021 20:19:19
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'will complete' (Site from DM).	Naomi Kown (b) (4) (b) (4)	11 Mar 2021 20:19:09

US3422101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:16

[Concomitant Medication](#)

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)	01 Mar 2021 19:57:35
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:55:37
User entered 'I'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00



**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered '0'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:45:24
User entered empty.	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

US3422101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:16

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:33:32
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User closed query 'Per DM CLR: Narrative = PILONIDAL CYST EXCISION ON 12FEB2021. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 10:32:51
Query 'Per DM CLR: Narrative = PILONIDAL CYST EXCISION ON 12FEB2021. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'it was originally on the con procedures instructed to remove. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:07:06
User opened query 'Per DM CLR: Narrative = PILONIDAL CYST EXCISION ON 12FEB2021. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 12:03:21
DataPoint Un-verified.	Naomi Kown (b) (4)	19 Mar 2021 17:06:25
User entered 'SUBJECT PRESENTED TO THE ED ON 13FEB2021 FOR ILEUS, STATUS POST SCHEDULED OUTPATIENT PROCEDURE FOR PILONIDAL CYST EXCISION ON 12FEB2021. POST -PROCEDURE SUBJECT TOOK OXYCODONE FOR PAIN MANAGEMENT, ILEUS RELATED TO POST-OP PAIN MANAGEMENT. Study site notified of surgery and hospitalization on 19FEB2021' reason for change: New Information	(b) (4) Naomi Kown (b) (4)	19 Mar 2021 17:06:25
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:45:24
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)	12 Mar 2021 14:50:51

US3422101

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:16

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 14:50:44
User entered 'SUBJECT PRESENTED TO THE ED ON 13FEB2021 FOR ILEUS, STATUS POST SCHEDULED OUTPATIENT PROCEDURE FOR PILONIDAL CYST EXCISION ON 12FEB2021. Post -procedure subject took oxycodone for pain management, ileus related to post-op pain management' reason for change: New Information	(b) (4), (b) (6)	11 Mar 2021 21:08:52
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 19 testing performed on 02/13/21 at 20:24, not detected using hologic panther covid-19 test. ' (Site from Safety).	Naomi Kown (b) (4) (b) (4)	11 Mar 2021 20:37:19
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no relevants labs, ct scan was sent with medical records.' (Site from Safety).	Naomi Kown (b) (4) (b) (4)	11 Mar 2021 20:19:51
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 Mar 2021 19:58:07
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 Mar 2021 19:57:16
User entered 'Subject presented to the ED on 13FEB2021 for ileus, status post scheduled outpatient procedure for pilonidal cyst excision on 12FEB2021.'	Naomi Kown (b) (4) (b) (4)	20 Feb 2021 16:16:00

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Feb 2021 16:16:00

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Feb 2021 16:16:00

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Feb 2021 16:16:00



US3422101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:32:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:02:56
User coded data point as SOC: Psychiatric disorders, HLG: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar II disorder, LLT: Bipolar II disorder - version MedDRA\23.0.	Coder Import (b) (4)	24 Mar 2021 08:34:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Mar 2021 08:34:30
Data point term sent to Coder	System	19 Mar 2021 17:26:44
User entered 'Worsening Bipolar Disorder II'	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:02:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	01 Apr 2021 17:03:01
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:03:07
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 17:26:35

US3422101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:32:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:03:10
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Mar 2021 17:27:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Mar 2021 17:27:27
User entered '15 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 17:27:27
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Mar 2021 17:26:35
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:03:14
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:03:18
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	19 Mar 2021 17:27:27
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	19 Mar 2021 17:26:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 17:26:35



US3422101

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:32:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:03:21
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Mar 2021 17:27:27
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	19 Mar 2021 17:27:27
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 17:27:27
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Mar 2021 17:26:35
User entered '15 Dec 2020'	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	01 Apr 2021 17:03:23
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:04:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	01 Apr 2021 17:04:27
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:04:32
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	01 Apr 2021 17:04:33
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:04:35
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 17:26:35



**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 17:04:37
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:04:38
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	01 Apr 2021 17:04:41
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:04:43
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:04:45
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:04:47
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:04:49
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	01 Apr 2021 17:05:00
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	19 Mar 2021 17:26:35



**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:05:02
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:05:05
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:05:08
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	01 Apr 2021 17:05:52
User entered 'I'	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:06:02
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:06:04
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	01 Apr 2021 17:06:12
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 17:06:27
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 17:26:35



**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Mar 2021 17:26:35

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Mar 2021 17:26:35

US3422101

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Streptococcal infections, PT: Pharyngitis streptococcal, LLT: Streptococcal pharyngitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 16:28:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:28:39
Data point term sent to Coder	System	20 Apr 2021 16:28:15
User entered 'Streptococcal pharyngitis'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

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

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34



**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

US3422101

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34



**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

US3422101

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34



**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

US3422101

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34



**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 16:27:34

**US3422101**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 16:27:34

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:32:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:46:18
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:16:23
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = 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)	11 Mar 2021 06:25:11
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = 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).	April Hanlotxomphou (b) (4)	10 Mar 2021 18:05:40
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = 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)	17 Feb 2021 22:48:37
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	25 Aug 2020 17:23:14

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: PREGABALIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 05:33:57
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 Aug 2020 05:33:57
Data point term sent to Coder	System	25 Aug 2020 17:28:26
User entered 'Pregablin'	Cindy Trimmer (b) (4) (b) (4)	25 Aug 2020 17:28:09

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:28:09
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Anxiety'	Cindy Trimmer (b) (4)	25 Aug 2020 17:28:09
	(b) (4)	



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '300'	Cindy Trimmer (b) (4)	25 Aug 2020 17:28:09
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:28:09
	(b) (4)	

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:28:09
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'twice daily (BID)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:28:09
	(b) (4)	

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:28:09
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:28:09
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:32:16**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:28:09
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'un UNK 2018' reason for change:	Cindy Trimmer (b) (4)	16 Oct 2020 18:17:17
Data Entry Error	(b) (4)	
User entered '30 Jun 2018'	Cindy Trimmer (b) (4)	25 Aug 2020 17:28:09
	(b) (4)	



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	Cindy Trimmer (b) (4)	25 Aug 2020 17:28:09
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:28:09
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:28:09
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:28:09
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Aug 2020 17:28:09

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 17:28:09

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 17:28:09

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: LAMOTRIGINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 10:40:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 10:40:49
Data point term sent to Coder	System	25 Aug 2020 17:29:27
User entered 'Lamotrigine'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:05
	(b) (4)	



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:05
	(b) (4)	

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Bipolar Disorder II'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:05
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '300'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:05
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:05
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:32:16**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:05
	(b) (4)	

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'once daily (QD)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:05
	(b) (4)	

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:05
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:05
	(b) (4)	



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:32:16**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:05
	(b) (4)	

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'un UNK 2011' reason for change:	Cindy Trimmer (b) (4)	16 Oct 2020 18:17:30
Data Entry Error	(b) (4)	
User entered '30 Jun 2011'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:05
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:05
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:05
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:32:16**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:05
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:05
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 17:29:05

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 17:29:05



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 17:29:05

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 14:02:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 14:02:42
Data point term sent to Coder	System	25 Aug 2020 17:30:33
User entered 'Topiramate'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:59
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:59
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Obsessive Compulsive Disorder'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:59
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '50'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:59
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:59
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:32:16**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:59
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'once daily (QD)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:59
	(b) (4)	



US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:59
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:59
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:32:16**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:59
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'un UNK 2018' reason for change:	Cindy Trimmer (b) (4)	16 Oct 2020 18:24:19
Data Entry Error	(b) (4)	
User entered '30 Jun 2018'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:59
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:59
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:59
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:32:16**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:59
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:29:59
	(b) (4)	



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 17:29:59

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 17:29:59

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 17:29:59

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: PROPRANOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 17:32:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 17:32:33
Data point term sent to Coder	System	25 Aug 2020 17:31:36
User entered 'Propranolol'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:03
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:03
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Anxiety'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:03
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '120'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:03
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:03
	(b) (4)	



US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:03
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'once daily (QD)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:03
	(b) (4)	

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:03
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:03
	(b) (4)	

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:03
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'un UNK 2017' reason for change:	Cindy Trimmer (b) (4)	16 Oct 2020 18:24:31
Data Entry Error	(b) (4)	
User entered '30 Jun 2017'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:03
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:03
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:03
	(b) (4)	



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:03
	(b) (4)	

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:03
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 17:31:03

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 17:31:03

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 17:31:03

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 17:33:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 17:33:34
Data point term sent to Coder	System	25 Aug 2020 17:32:40
User entered 'Trazadone'	Cindy Trimmer (b) (4) (b) (4)	25 Aug 2020 17:31:42

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:42
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Anxiety'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:42
	(b) (4)	



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '100'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:42
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:42
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:32:16**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:42
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'as needed (PRN)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:42
	(b) (4)	

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:42
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:42
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:32:16**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:42
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'un UNK 2015' reason for change:	Cindy Trimmer (b) (4)	16 Oct 2020 18:24:40
Data Entry Error	(b) (4)	
User entered '30 Jun 2015'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:42
	(b) (4)	



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:42
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:42
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:42
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:31:42
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:31:42

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:31:42

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:31:42

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 17:34:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Aug 2020 17:34:31
Data point term sent to Coder	System	25 Aug 2020 17:33:42
User entered 'Lorazepam'	Cindy Trimmer (b) (4)	25 Aug 2020 17:32:43
	(b) (4)	



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:32:43
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Anxiety'	Cindy Trimmer (b) (4)	25 Aug 2020 17:32:43
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'I'	Cindy Trimmer (b) (4)	25 Aug 2020 17:32:43
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:32:43
	(b) (4)	

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:32:43
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'as needed (PRN)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:32:43
	(b) (4)	

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:32:43
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:32:43
	(b) (4)	



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:32:16**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:32:43
	(b) (4)	

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'un UNK 2011' reason for change:	Cindy Trimmer (b) (4)	16 Oct 2020 18:24:49
Data Entry Error	(b) (4)	
User entered '30 Jun 2011'	Cindy Trimmer (b) (4)	25 Aug 2020 17:32:43
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	Cindy Trimmer (b) (4)	25 Aug 2020 17:32:43
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:32:43
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:32:16**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:32:43
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:32:43
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:32:43

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:32:43



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:32:43

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 17:49:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 17:49:43
Data point term sent to Coder	System	25 Aug 2020 17:33:45
User entered 'Sumatriptain'	Cindy Trimmer (b) (4)	25 Aug 2020 17:33:33
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:33:33
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Migraines'	Cindy Trimmer (b) (4)	25 Aug 2020 17:33:33
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '50'	Cindy Trimmer (b) (4)	25 Aug 2020 17:33:33
	(b) (4)	

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:33:33
	(b) (4)	

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:33:33
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'as needed (PRN)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:33:33
	(b) (4)	



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:32:16**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:33:33
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:33:33
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:32:16**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:33:33
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '23 Jan 2020'	Cindy Trimmer (b) (4)	25 Aug 2020 17:33:33
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	Cindy Trimmer (b) (4)	25 Aug 2020 17:33:33
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:33:33
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:32:16**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4)	25 Aug 2020 17:33:33
	(b) (4)	

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	Cindy Trimmer (b) (4)	25 Aug 2020 17:33:33
	(b) (4)	



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:33:33

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:33:33

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 17:33:33

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:38
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
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)	10 Mar 2021 18:21:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 18:21:54
Data point term sent to Coder	System	10 Mar 2021 18:05:53
Coding entries removed.	April Hanlotxomphou (b) (4)	10 Mar 2021 18:05:30
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)	09 Nov 2020 21:37:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 21:37:37
Data point term sent to Coder	System	09 Nov 2020 21:36:15
Coding entries removed.	Anna Gallion (b) (4) (b) (4)	09 Nov 2020 21:36:13
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)	24 Sep 2020 17:01:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 17:01:50
Data point term sent to Coder	System	24 Sep 2020 17:00:45
User entered 'Acetaminophen'	Cindy Trimmer (b) (4) (b) (4)	24 Sep 2020 17:00:06

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2219 of 2667

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:38
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	24 Sep 2020 17:00:06

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:38
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the GENERALIZED MYALGIAS/PAIN AT INJECTION SITE 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 or 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 GENERALIZED MYALGIAS/PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Apr 2021 11:10:10
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the GENERALIZED MYALGIAS/PAIN AT INJECTION SITE 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 or 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 GENERALIZED MYALGIAS/PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' answered with 'within reacto period. Not an AE.' (Site from DM).	Anna Gallion (b) (4) (b) (4)	30 Mar 2021 19:28:21

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:16

[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 time frame. If the GENERALIZED MYALGIAS/PAIN AT INJECTION SITE 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 or 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 GENERALIZED MYALGIAS/PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:04:13
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the GENERALIZED MYALGIAS/PAIN AT INJECTION SITE 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 or 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 GENERALIZED MYALGIAS/PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' canceled (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:04:09

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:16

[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 time frame. If the GENERALIZED MYALGIAS/PAIN AT INJECTION SITE 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 or 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 GENERALIZED MYALGIAS/PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 06:04:07
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'GENERALIZED MYALGIAS/PAIN AT INJECTION SITE' reason for change: Data Entry Error	April Hanlotxomphou	10 Mar 2021 18:05:30
	(b) (4)	
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MYALGIAS 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 MYALGIAS did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 06:37:41
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please provide the specific location of MYALGIAS (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Indication and ensure to reconcile with ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 06:37:37
	(b) (4), (b) (6)	



US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:16

[Indication](#)

Audit	User	Time (GMT)
Query ' Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MYALGIAS 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 MYALGIAS did not meet the AE reporting criteria.' answered with 'solicited adverse reaction of MYALGIAS did not meet the AE reporting criteria' (Site from DM).	Anna Gallion (b) (4) (b) (4)	09 Nov 2020 21:38:35
Query 'Per DM CLR: Please provide the specific location of MYALGIAS (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Indication and ensure to reconcile with ' answered with 'updated' (Site from DM).	Anna Gallion (b) (4) (b) (4)	09 Nov 2020 21:38:26
User entered 'generalized MYALGIAS' reason for change: Data Entry Error	Anna Gallion (b) (4) (b) (4)	09 Nov 2020 21:36:13
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MYALGIAS 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 MYALGIAS did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:53:45
User opened query 'Per DM CLR: Please provide the specific location of MYALGIAS (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Indication and ensure to reconcile with ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:53:35
User entered 'Myalgias'	Cindy Trimmer (b) (4) (b) (4)	24 Sep 2020 17:00:06

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2224 of 2667

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:38
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '1000'	Cindy Trimmer (b) (4) (b) (4)	24 Sep 2020 17:00:06

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:38
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	Cindy Trimmer (b) (4) (b) (4)	24 Sep 2020 17:00:06

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:32:16**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:38
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	24 Sep 2020 17:00:06

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:38
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'as needed (PRN)'	Cindy Trimmer (b) (4) (b) (4)	24 Sep 2020 17:00:06

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:32:16**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:38
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	24 Sep 2020 17:00:06

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:38
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Oral (ORAL)'	Cindy Trimmer (b) (4) (b) (4)	24 Sep 2020 17:00:06

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:32:16**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:38
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	24 Sep 2020 17:00:06



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:38
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '22 Sep 2020'	Cindy Trimmer (b) (4) (b) (4)	24 Sep 2020 17:00:06

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:38
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	24 Sep 2020 17:00:06

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:38
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)' reason for change: Data Entry Error	Anna Gallion (b) (4) (b) (4)	09 Nov 2020 21:37:54
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	24 Sep 2020 17:00:06

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:38
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '24 Sep 2020' reason for change: Data Entry Error	April Hanlotxomphou (b) (4)	10 Mar 2021 18:05:30
User entered '23 Sep 2020' reason for change: Data Entry Error	Anna Gallion (b) (4) (b) (4)	09 Nov 2020 21:37:54
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	24 Sep 2020 17:00:06

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:38
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	24 Sep 2020 17:00:06

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:38
User entered empty.	System	24 Sep 2020 17:00:06

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:38
User entered empty.	System	24 Sep 2020 17:00:06

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:38
User entered empty.	System	24 Sep 2020 17:00:06



US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:43
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Oct 2020 07:11:41
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 Oct 2020 07:11:41
Data point term sent to Coder	System	16 Oct 2020 18:36:04
User entered 'Influenza vaccine'	Cindy Trimmer (b) (4) (b) (4)	16 Oct 2020 18:35:05

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:43
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	Cindy Trimmer (b) (4) (b) (4)	16 Oct 2020 18:35:05

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:43
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'health maintenance'	Cindy Trimmer (b) (4) (b) (4)	16 Oct 2020 18:35:05

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:43
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'I'	Cindy Trimmer (b) (4) (b) (4)	16 Oct 2020 18:35:05

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:43
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Other (OTHER)'	Cindy Trimmer (b) (4) (b) (4)	16 Oct 2020 18:35:05

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:32:16**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:43
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'injection'	Cindy Trimmer (b) (4) (b) (4)	16 Oct 2020 18:35:05

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:43
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'once (ONCE)'	Cindy Trimmer (b) (4) (b) (4)	16 Oct 2020 18:35:05

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:32:16**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:43
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	16 Oct 2020 18:35:05



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:43
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Intramuscular (INTRAMUSCULAR)'	Cindy Trimmer (b) (4) (b) (4)	16 Oct 2020 18:35:05

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:32:16**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:43
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	Cindy Trimmer (b) (4) (b) (4)	16 Oct 2020 18:35:05

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:43
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '12 Oct 2020'	Cindy Trimmer (b) (4) (b) (4)	16 Oct 2020 18:35:05

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:43
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	Cindy Trimmer (b) (4) (b) (4)	16 Oct 2020 18:35:05

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:43
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	16 Oct 2020 18:35:05

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:43
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '12 Oct 2020'	Cindy Trimmer (b) (4) (b) (4)	16 Oct 2020 18:35:05

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:43
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	Cindy Trimmer (b) (4) (b) (4)	16 Oct 2020 18:35:05

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:43
User entered empty.	System	16 Oct 2020 18:35:05



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:43
User entered empty.	System	16 Oct 2020 18:35:05

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:43
User entered empty.	System	16 Oct 2020 18:35:05

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:32:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:47
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:04:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 21:04:48
Data point term sent to Coder	System	18 Nov 2020 21:03:25
User entered 'amoxicillin'	(b) (4), (b) (6)	18 Nov 2020 21:03:22

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:47
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 21:03:22

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:47
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'streptococcal pharyngitis'	(b) (4), (b) (6)	18 Nov 2020 21:03:22

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:47
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '875'	(b) (4), (b) (6)	18 Nov 2020 21:03:22

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:47
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	(b) (4), (b) (6)	18 Nov 2020 21:03:22

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:32:16**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:47
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 21:03:22



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:47
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'once daily (QD)'	(b) (4), (b) (6)	18 Nov 2020 21:03:22

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:32:16**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:47
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 21:03:22

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:47
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	18 Nov 2020 21:03:22

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:32:16**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:47
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 21:03:22

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:47
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '16 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 21:03:22

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:47
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 21:03:22

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:47
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	22 Feb 2021 19:31:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 21:03:22

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:47
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '26 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	22 Feb 2021 19:31:28
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 21:03:22



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:47
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	18 Nov 2020 21:03:22

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:47
User entered '1'	System	18 Nov 2020 21:03:22

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:47
User entered '1'	System	18 Nov 2020 21:03:22

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:47
User entered '804 (804)'	System	18 Nov 2020 21:03:22

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 19:22:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	08 Mar 2021 19:22:41
Data point term sent to Coder	System	08 Mar 2021 19:22:06
User entered 'Loratadine'	(b) (4), (b) (6)	08 Mar 2021 19:21:26

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	08 Mar 2021 19:21:26

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Seasonal Allergies'	(b) (4), (b) (6)	08 Mar 2021 19:21:26

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '10'	(b) (4), (b) (6)	08 Mar 2021 19:21:26



US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Mar 2021 19:21:26

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 19:21:26

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'once (ONCE)'	(b) (4), (b) (6)	08 Mar 2021 19:21:26

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 19:21:26

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Mar 2021 19:21:26

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 19:21:26

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'un UNK 1990'	(b) (4), (b) (6)	08 Mar 2021 19:21:26

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	(b) (4), (b) (6)	08 Mar 2021 19:21:26



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 19:21:26

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 19:21:26

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	08 Mar 2021 19:21:26

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 19:21:26

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 19:21:26

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 19:21:26

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: KETAMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 12:34:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 12:34:40
Data point term sent to Coder	System	19 Mar 2021 17:01:59
Coding entries removed.	Naomi Kown (b) (4) (b) (4)	19 Mar 2021 17:01:07
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: KETAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:53:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 07:53:53
Data point term sent to Coder	System	08 Mar 2021 19:24:13
User entered 'Ketamine'	(b) (4), (b) (6)	08 Mar 2021 19:23:58

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	08 Mar 2021 19:23:58



US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:16

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Please add worsening depression as an AE. Please also add it to subject's medical history. ' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:45:21
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
Query 'Please add worsening depression as an AE. Please also add it to subject's medical history. ' answered by data change (Site from CRA).	(b) (4) System	19 Mar 2021 17:01:07
User entered 'WORSENING bipolar disorder II' reason for change: Data Entry Error	Naomi Kown (b) (4)	19 Mar 2021 17:01:07
User opened query 'Please add worsening depression as an AE. Please also add it to subject's medical history. ' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 16:57:48
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 16:51:38
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'worsening Depression'	(b) (4), (b) (6)	08 Mar 2021 19:23:58

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '80'	(b) (4), (b) (6)	08 Mar 2021 19:23:58

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Mar 2021 19:23:58

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 19:23:58

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'every week (QS)'	(b) (4), (b) (6)	08 Mar 2021 19:23:58

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 19:23:58

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	08 Mar 2021 19:23:58

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:32:16**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 19:23:58



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '11 Jan 2021'	(b) (4), (b) (6)	08 Mar 2021 19:23:58

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	(b) (4), (b) (6)	08 Mar 2021 19:23:58

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 19:23:58

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 19:23:58

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	08 Mar 2021 19:23:58

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Mar 2021 19:23:58

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Mar 2021 19:23:58

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	08 Mar 2021 19:23:58



US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: LITHIUM, PRODUCT: LITHIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Apr 2021 16:00:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:00:38
Data point term sent to Coder	System	05 Apr 2021 18:27:01
Coding entries removed.	(b) (4), (b) (6)	05 Apr 2021 18:26:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: LITHIUM, PRODUCT: LITHIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 14:00:31
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 Mar 2021 14:00:31
Data point term sent to Coder	System	19 Mar 2021 17:01:58
Coding entries removed.	Naomi Kown (b) (4) (b) (4)	19 Mar 2021 17:01:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: LITHIUM, PRODUCT: LITHIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 13:40:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 13:40:43
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
Data point term sent to Coder	System	08 Mar 2021 19:27:15
User entered 'Lithium'	(b) (4), (b) (6)	08 Mar 2021 19:27:12

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	08 Mar 2021 19:27:12

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
	(b) (4)	
DataPoint Un-verified.	Naomi Kown (b) (4)	19 Mar 2021 17:01:37
	(b) (4)	
User entered 'WORSENING bipolar disorder II'	Naomi Kown (b) (4)	19 Mar 2021 17:01:37
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'worsening depression'	(b) (4), (b) (6)	08 Mar 2021 19:27:12

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '300'	(b) (4), (b) (6)	08 Mar 2021 19:27:12

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Mar 2021 19:27:12

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 19:27:12

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:16

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Once daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 09:55:35
Query 'Per CDM: Once daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'updated' (Site from DM). DataPoint Un-verified.	Clarence Creech (b) (4) (b) (4) (b) (4), (b) (6)	08 Apr 2021 20:48:36 08 Apr 2021 16:29:15
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:28:58
User opened query 'Per CDM: Once daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 17:42:12 16 Mar 2021 16:29:23
User entered 'other (OTHER)'	(b) (4), (b) (6)	08 Mar 2021 19:27:12

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Un-verified.	(b) (4)	08 Apr 2021 16:28:58
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:28:58
DataPoint Verified.		16 Mar 2021 16:29:23
User entered 'qhs'		08 Mar 2021 19:27:12



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Un-verified.	(b) (4)	05 Apr 2021 18:26:49
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 18:26:49
DataPoint Verified.		16 Mar 2021 16:29:23
User entered 'Other (OTHER)'		08 Mar 2021 19:27:12

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User closed query 'Per DM CLR: Please specify CR and review route if this is typically administered as indicated. Please update as appropriate. ' (Site from DM).	(b) (4)	06 Apr 2021 12:25:20
Query 'Per DM CLR: Please specify CR and review route if this is typically administered as indicated. Please update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:27:04
DataPoint Un-verified.		05 Apr 2021 18:26:49
User entered empty; reason for change Data Entry Error		05 Apr 2021 18:26:49
User opened query 'Per DM CLR: Please specify CR and review route if this is typically administered as indicated. Please update as appropriate. ' (Site from DM).		02 Apr 2021 01:05:34
DataPoint Verified.		16 Mar 2021 16:29:23
User entered 'CR'		08 Mar 2021 19:27:12

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	16 Mar 2021 16:29:23
User entered 'un Dec 2020'	(b) (4), (b) (6)	08 Mar 2021 19:27:12

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	16 Mar 2021 16:29:23
User entered '0'	(b) (4), (b) (6)	08 Mar 2021 19:27:12

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 19:27:12

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 19:27:12

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	08 Mar 2021 19:27:12

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 16:28:58
User entered empty.	System	08 Mar 2021 19:27:12



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 16:28:58
User entered empty.	System	08 Mar 2021 19:27:12

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 16:28:58
User entered empty.	System	08 Mar 2021 19:27:12

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:56
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Mar 2021 05:39:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 05:39:25
Data point term sent to Coder	System	19 Mar 2021 17:22:31
Data point term sent to Coder	System	19 Mar 2021 17:03:00
Coding entries removed.	Naomi Kown (b) (4) (b) (4)	19 Mar 2021 17:02:18
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 19:29:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 19:29:41
Data point term sent to Coder	System	08 Mar 2021 19:29:18
User entered 'Oxycodone'	(b) (4), (b) (6)	08 Mar 2021 19:28:38

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:56
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	08 Mar 2021 19:28:38

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:32:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:56
User closed query 'Please update to reflect indication as "post surgery pain" rather than just "pain". ' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:37:45
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User entered 'excision of pilondal cyst' reason for change: Data Entry Error	(b) (4)	
Query 'Please update to reflect indication as "post surgery pain" rather than just "pain". ' answered by data change (Site from CRA).	Naomi Kown (b) (4)	19 Mar 2021 17:21:54
	(b) (4)	
	System	19 Mar 2021 17:02:18
User entered 'post surgery pain' reason for change: Data Entry Error	Naomi Kown (b) (4)	19 Mar 2021 17:02:18
	(b) (4)	
User opened query 'Please update to reflect indication as "post surgery pain" rather than just "pain". ' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 17:11:14
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 17:10:41
DataPoint Verified.		16 Mar 2021 16:29:23
User entered 'Pain'		08 Mar 2021 19:28:38

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:56
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '5'		08 Mar 2021 19:28:38

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:56
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Mar 2021 19:28:38

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:32:16**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:56
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 19:28:38



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:56
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'as needed (PRN)'	(b) (4), (b) (6)	08 Mar 2021 19:28:38

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:32:16**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:56
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 19:28:38

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:56
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Mar 2021 19:28:38

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:32:16**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:56
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	08 Mar 2021 19:28:38

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:32:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:56
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Un-verified.	(b) (4)	
	Naomi Kown (b) (4)	19 Mar 2021 17:21:54
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4)	19 Mar 2021 17:21:54
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '13 Feb 2021'	(b) (4), (b) (6)	08 Mar 2021 19:28:38

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:56
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	(b) (4), (b) (6)	08 Mar 2021 19:28:38

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:56
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	08 Mar 2021 19:28:38

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:56
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '16 Feb 2021'	(b) (4), (b) (6)	08 Mar 2021 19:28:38



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:56
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	08 Mar 2021 19:28:38

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:56
User entered empty.	System	08 Mar 2021 19:28:38

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:56
User entered empty.	System	08 Mar 2021 19:28:38

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:41:56
User entered empty.	System	08 Mar 2021 19:28:38

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:05
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: ENEMAS, PRODUCT: BISACODYL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 05:43:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 05:43:08
Data point term sent to Coder	System	11 Mar 2021 20:46:16
User entered 'Bisacodyl'	(b) (4), (b) (6)	11 Mar 2021 20:45:32

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:05
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 20:45:32

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:05
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Ileus'	(b) (4), (b) (6)	11 Mar 2021 20:45:32

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:05
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '10'	(b) (4), (b) (6)	11 Mar 2021 20:45:32



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:05
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Mar 2021 20:45:32

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:32:16**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:05
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:45:32

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:05
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'once (ONCE)'	(b) (4), (b) (6)	11 Mar 2021 20:45:32

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:32:16**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:05
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:45:32

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:05
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Rectal (RECTAL)'	(b) (4), (b) (6)	11 Mar 2021 20:45:32

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:32:16**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:05
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:45:32

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:05
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '14 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 20:45:32

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:05
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 20:45:32



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:05
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 20:45:32

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:05
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '14 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 20:45:32

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:05
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 12:25:43
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:21:14
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 18:20:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 18:20:59
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:06:26

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2362 of 2667

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 20:45:32

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:05
User entered empty.	System	11 Mar 2021 20:45:32

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:05
User entered empty.	System	11 Mar 2021 20:45:32

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:05
User entered empty.	System	11 Mar 2021 20:45:32

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:19
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:00:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:00:59
Data point term sent to Coder	System	11 Mar 2021 20:49:19
User entered 'ketorolac'	(b) (4), (b) (6)	11 Mar 2021 20:48:23



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:19
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 20:48:23

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:19
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Ileus'	(b) (4), (b) (6)	11 Mar 2021 20:48:23

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:19
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '15'	(b) (4), (b) (6)	11 Mar 2021 20:48:23

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:19
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Mar 2021 20:48:23

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:32:16**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:19
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:48:23

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:19
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'once (ONCE)'	(b) (4), (b) (6)	11 Mar 2021 20:48:23

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:32:16**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:19
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:48:23

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:19
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	11 Mar 2021 20:48:23



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:32:16**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:19
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:48:23

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:19
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '14 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 20:48:23

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:19
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 20:48:23

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:19
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 20:48:23

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:19
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '14 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 20:48:23

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:19
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 12:25:48
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:28:39
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 18:27:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 18:27:51
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:06:41

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2381 of 2667

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 20:48:23

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:19
User entered empty.	System	11 Mar 2021 20:48:23



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:19
User entered empty.	System	11 Mar 2021 20:48:23

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:19
User entered empty.	System	11 Mar 2021 20:48:23

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:25
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: LACTULOSE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Mar 2021 11:06:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:06:57
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
Data point term sent to Coder	System	11 Mar 2021 20:50:20
User entered 'Lactulose'	(b) (4), (b) (6)	11 Mar 2021 20:49:45

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:25
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 20:49:45

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:25
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Ileus'	(b) (4), (b) (6)	11 Mar 2021 20:49:45

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:25
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '20'	(b) (4), (b) (6)	11 Mar 2021 20:49:45

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:25
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'g (g)'	(b) (4), (b) (6)	11 Mar 2021 20:49:45

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:32:16**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:25
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:49:45



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:25
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'once (ONCE)'	(b) (4), (b) (6)	11 Mar 2021 20:49:45

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:32:16**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:25
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:49:45

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:25
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Mar 2021 20:49:45

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:32:16**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:25
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:49:45

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:25
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '15 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 20:49:45

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:25
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 20:49:45

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:25
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 20:49:45

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:25
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '15 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 20:49:45



US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:25
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 12:25:53
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:29:41
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 18:29:28
User entered 'No (N)' reason for change: Data Entry Error		05 Apr 2021 18:29:28
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).		30 Mar 2021 06:06:55

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2400 of 2667

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 20:49:45

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:25
User entered empty.	System	11 Mar 2021 20:49:45

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:25
User entered empty.	System	11 Mar 2021 20:49:45

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:25
User entered empty.	System	11 Mar 2021 20:49:45

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:32
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM CITRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 08:38:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 08:38:40
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
Data point term sent to Coder	System	11 Mar 2021 20:52:22
User entered 'Magnesium Citrate'	(b) (4), (b) (6)	11 Mar 2021 20:51:31

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:32
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 20:51:31

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:32
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Ileus'	(b) (4), (b) (6)	11 Mar 2021 20:51:31



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:32
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '296'	(b) (4), (b) (6)	11 Mar 2021 20:51:31

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:32
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mL (mL)'	(b) (4), (b) (6)	11 Mar 2021 20:51:31

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:32:16**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:32
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:51:31

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:32
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'once (ONCE)'	(b) (4), (b) (6)	11 Mar 2021 20:51:31

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:32:16**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:32
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:51:31

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:32
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Mar 2021 20:51:31

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:32:16**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:32
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:51:31

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:32
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '14 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 20:51:31



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:32
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 20:51:31

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:32
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 20:51:31

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:32
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '14 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 20:51:31

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:32
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 12:25:58
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:31:17
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 18:30:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 18:30:54
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:07:07

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2419 of 2667

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 20:51:31

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:32
User entered empty.	System	11 Mar 2021 20:51:31

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:32
User entered empty.	System	11 Mar 2021 20:51:31

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:32
User entered empty.	System	11 Mar 2021 20:51:31



US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:45
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM HYDROXIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 08:39:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 08:39:41
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
Data point term sent to Coder	System	11 Mar 2021 20:54:27
User entered 'Magnesium Hydroxide'	(b) (4), (b) (6)	11 Mar 2021 20:54:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:45
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 20:54:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:45
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Ileus'	(b) (4), (b) (6)	11 Mar 2021 20:54:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:45
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '30'	(b) (4), (b) (6)	11 Mar 2021 20:54:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:45
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mL (mL)'	(b) (4), (b) (6)	11 Mar 2021 20:54:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:32:16**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:45
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:54:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:45
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'twice daily (BID)'	(b) (4), (b) (6)	11 Mar 2021 20:54:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:32:16**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:45
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:54:08



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:45
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Mar 2021 20:54:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:32:16**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:45
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:54:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:45
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '13 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 20:54:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:45
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 20:54:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:45
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 20:54:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:45
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '14 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 20:54:08

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:45
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 12:26:03
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 18:31:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 18:31:56
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:07:36

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2438 of 2667

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 20:54:08



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:45
User entered '2'	System	11 Mar 2021 20:54:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:45
User entered '1'	System	11 Mar 2021 20:54:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:45
User entered '804 (804)'	System	11 Mar 2021 20:54:08

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:51
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:58:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:58:51
Data point term sent to Coder	System	11 Mar 2021 20:56:33
User entered 'Methocarbamol'	(b) (4), (b) (6)	11 Mar 2021 20:56:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:51
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 20:56:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:51
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Ileus'	(b) (4), (b) (6)	11 Mar 2021 20:56:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:51
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '500'	(b) (4), (b) (6)	11 Mar 2021 20:56:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:51
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Mar 2021 20:56:11



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:32:16**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:51
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:56:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:51
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'once (ONCE)'	(b) (4), (b) (6)	11 Mar 2021 20:56:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:32:16**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:51
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:56:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:51
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	11 Mar 2021 20:56:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:32:16**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:51
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:56:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:51
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '14 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 20:56:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:51
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 20:56:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:51
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 20:56:11



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:51
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '14 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 20:56:11

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:51
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 12:26:08
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:34:08
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 18:33:52
User entered 'No (N)' reason for change: Data Entry Error		05 Apr 2021 18:33:52
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).		30 Mar 2021 06:07:47

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2457 of 2667

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 20:56:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:51
User entered empty.	System	11 Mar 2021 20:56:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:51
User entered empty.	System	11 Mar 2021 20:56:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:42:51
User entered empty.	System	11 Mar 2021 20:56:11

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:01
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:58:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:58:52
Data point term sent to Coder	System	11 Mar 2021 20:58:36
User entered 'Methocarbamol'	(b) (4), (b) (6)	11 Mar 2021 20:58:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:01
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 20:58:08



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:01
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Ileus'	(b) (4), (b) (6)	11 Mar 2021 20:58:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:01
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '750'	(b) (4), (b) (6)	11 Mar 2021 20:58:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:01
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Mar 2021 20:58:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:32:16**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:01
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:58:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:01
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'once (ONCE)'	(b) (4), (b) (6)	11 Mar 2021 20:58:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:32:16**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:01
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:58:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:01
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	11 Mar 2021 20:58:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:32:16**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:01
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 20:58:08



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:01
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '14 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 20:58:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:01
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 20:58:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:01
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 20:58:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:01
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '14 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 20:58:08

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:01
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 12:26:13
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:35:23
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 18:35:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 18:35:01
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:07:58

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2476 of 2667

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 20:58:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:01
User entered empty.	System	11 Mar 2021 20:58:08

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:01
User entered empty.	System	11 Mar 2021 20:58:08



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:01
User entered empty.	System	11 Mar 2021 20:58:08

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:07
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
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: ONDASETRON [ONDANSETRON] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Mar 2021 12:18:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 12:18:37
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
Data point term sent to Coder	System	11 Mar 2021 21:00:37
User entered 'Ondasetron'	(b) (4), (b) (6)	11 Mar 2021 21:00:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:07
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 21:00:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:07
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Ileus'	(b) (4), (b) (6)	11 Mar 2021 21:00:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:07
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '4'	(b) (4), (b) (6)	11 Mar 2021 21:00:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:07
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Mar 2021 21:00:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:32:16**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:07
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 21:00:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:07
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'once (ONCE)'	(b) (4), (b) (6)	11 Mar 2021 21:00:11



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:32:16**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:07
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 21:00:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:07
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	11 Mar 2021 21:00:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:32:16**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:07
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 21:00:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:07
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '14 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 21:00:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:07
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 21:00:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:07
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 21:00:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:07
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '14 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 21:00:11

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:07
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 12:26:19
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:36:34
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 18:36:08
User entered 'No (N)' reason for change: Data Entry Error		05 Apr 2021 18:36:08
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).		30 Mar 2021 06:08:11

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2495 of 2667



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 21:00:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:07
User entered empty.	System	11 Mar 2021 21:00:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:07
User entered empty.	System	11 Mar 2021 21:00:11

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:07
User entered empty.	System	11 Mar 2021 21:00:11

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:14
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 21:02:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 21:02:54
Data point term sent to Coder	System	11 Mar 2021 21:01:39
User entered 'Miralax'	(b) (4), (b) (6)	11 Mar 2021 21:01:35

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:14
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 21:01:35

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:14
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Ileus'	(b) (4), (b) (6)	11 Mar 2021 21:01:35

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:14
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '17'	(b) (4), (b) (6)	11 Mar 2021 21:01:35



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:14
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'g (g)'	(b) (4), (b) (6)	11 Mar 2021 21:01:35

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:32:16**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:14
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 21:01:35

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:14
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'as needed (PRN)'	(b) (4), (b) (6)	11 Mar 2021 21:01:35

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:32:16**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:14
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 21:01:35

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:14
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Mar 2021 21:01:35

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:32:16**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:14
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 21:01:35

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:14
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '14 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 21:01:35

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:14
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 21:01:35



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:14
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 21:01:35

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:14
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '15 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 21:01:35

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:14
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 12:26:24
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:38:01
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 18:37:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 18:37:22
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:08:24

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2514 of 2667

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 21:01:35

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:14
User entered empty.	System	11 Mar 2021 21:01:35

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:14
User entered empty.	System	11 Mar 2021 21:01:35

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:14
User entered empty.	System	11 Mar 2021 21:01:35

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:20
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: DOCUSATE;SENNOSIDE A+B - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Mar 2021 09:37:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:37:30
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
Data point term sent to Coder	System	11 Mar 2021 21:04:42
User entered 'sennoside-docusate'	(b) (4), (b) (6)	11 Mar 2021 21:04:17



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:20
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 21:04:17

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:20
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Ileus'	(b) (4), (b) (6)	11 Mar 2021 21:04:17

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:20
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '100'	(b) (4), (b) (6)	11 Mar 2021 21:04:17

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:20
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Mar 2021 21:04:17

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:32:16**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:20
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 21:04:17

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:20
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Mar 2021 21:04:17

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:32:16**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:20
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 21:04:17

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:20
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Mar 2021 21:04:17



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:32:16**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:20
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 21:04:17

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:20
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '13 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 21:04:17

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:20
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 21:04:17

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:20
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 21:04:17

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:20
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '14 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 21:04:17

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:20
User closed query 'Per CDM: Response indicates updated ; However there is no update made. Please review and update this field to No per previous query if appropriate else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:55:53
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
Query 'Per CDM: Response indicates updated ; However there is no update made. Please review and update this field to No per previous query if appropriate else clarify. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:31:19
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 16:31:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:31:03
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate.	(b) (4), (b) (6)	06 Apr 2021 12:27:13
' (Site from DM).	(b) (4), (b) (6)	
User opened query 'Per CDM: Response indicates updated ; However there is no update made. Please review and update this field to No per previous query if appropriate else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 12:27:11

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:38:55
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate.	(b) (4), (b) (6)	30 Mar 2021 06:08:42
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 21:04:17

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:20
User entered '1'	System	11 Mar 2021 21:04:17



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:20
User entered '1'	System	11 Mar 2021 21:04:17

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:20
User entered '804 (804)'	System	11 Mar 2021 21:04:17

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:26
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: BUTYROPHENONE DERIVATIVES, PRODUCT: HALOPERIDOL, PRODUCTSYNONYM: HALDOL [HALOPERIDOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 12:11:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 12:11:58
Data point term sent to Coder	System	11 Mar 2021 21:05:43
User entered 'Haldol'	(b) (4), (b) (6)	11 Mar 2021 21:05:42

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:26
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 21:05:42

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:32:16**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:26
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Ileus'	(b) (4), (b) (6)	11 Mar 2021 21:05:42

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:26
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0.5'	(b) (4), (b) (6)	11 Mar 2021 21:05:42

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:32:16**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:26
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Mar 2021 21:05:42

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:32:16**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:26
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 21:05:42



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:32:16**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:26
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Mar 2021 21:05:42

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:32:16**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:26
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 21:05:42

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:26
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	11 Mar 2021 21:05:42

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:32:16**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:26
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 21:05:42

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:26
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '14 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 21:05:42

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:26
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 21:05:42

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:26
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 21:05:42

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:32:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:26
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered '15 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 21:05:42



US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:16

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:26
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 12:27:19
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:40:17
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 18:39:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 18:39:48
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please confirm if data is correct and update eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:08:58

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2552 of 2667

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:32:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:29:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 21:05:42

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:26
User entered '1'	System	11 Mar 2021 21:05:42

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:26
User entered '1'	System	11 Mar 2021 21:05:42

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:43:26
User entered '804 (804)'	System	11 Mar 2021 21:05:42

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 16:24:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 16:24:38
Data point term sent to Coder	System	20 Apr 2021 16:24:11
User entered 'Amoxicillin'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 16:24:00

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:32:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:00

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered 'streptococcal pharyngitis'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:00



US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered '500'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:00

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:00

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 16:24:00

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:00

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:24:00

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:32:16**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:00

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:32:16**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:00

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:00



**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:32:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:00

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:32:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:00

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 16:24:00

US3422101

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	22 Apr 2021 15:34:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:24:00

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:32:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Apr 2021 16:24:00

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 16:24:00

**US3422101**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:32:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 16:24:00

US3422101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:32:16

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:46:18
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
Signature has been broken.	(b) (4)	
	Cindy Trimmer (b) (4)	08 Apr 2021 16:41:22
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Cindy Trimmer (b) (4)	08 Apr 2021 16:41:22
	(b) (4)	
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Naomi Kown (b) (4)	19 Mar 2021 17:14:38
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	22 Feb 2021 19:31:56
User entered 'No (N)'	Cindy Trimmer (b) (4)	25 Aug 2020 18:44:43
	(b) (4)	



US3422101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:32:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Cindy Trimmer (b) (4)	08 Apr 2021 16:41:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Naomi Kown (b) (4)	19 Mar 2021 17:14:47
	(b) (4)	
User entered '12 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 19:32:46

US3422101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:32:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Cindy Trimmer (b) (4)	08 Apr 2021 16:41:42
	(b) (4)	
	Naomi Kown (b) (4)	19 Mar 2021 17:14:47
	(b) (4)	
User closed query 'Per ETRTR: Since procedure was related to SAE "Ileus", please go to SAE page and tick on "Concomitant Procedures" action taken checkbox, thanks.' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 14:46:57
Query 'Per ETRTR: Since procedure was related to SAE "Ileus", please go to SAE page and tick on "Concomitant Procedures" action taken checkbox, thanks.' answered with 'not related to SAE. Added comments to SAE, Post excision of pilonidal cyst, subject took oxycodone for pain management, ileus related to post-op pain management. ' (Site from CRA).	Naomi Kown (b) (4)	11 Mar 2021 20:27:53
	(b) (4)	
User opened query 'Per ETRTR: Since procedure was related to SAE "Ileus", please go to SAE page and tick on "Concomitant Procedures" action taken checkbox, thanks.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 20:46:01
User entered 'excision of pilonidal cyst'	(b) (4), (b) (6)	22 Feb 2021 19:32:46

US3422101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:32:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Cindy Trimmer (b) (4)	08 Apr 2021 16:41:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Naomi Kown (b) (4)	19 Mar 2021 17:14:47
	(b) (4)	
User entered 'Medical History (MH)'	(b) (4), (b) (6)	22 Feb 2021 19:32:46

US3422101

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:32:16

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 20:48:36
	(b) (4)	
DataPoint activated with code reason code Data required.	Cindy Trimmer (b) (4)	08 Apr 2021 16:41:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Naomi Kown (b) (4)	19 Mar 2021 17:14:47
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 19:32:46

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered		
'USA-US082-2021-MRNA-1273-P301000006'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Yes (Y)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33



**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Yes (Y)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Clarence'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Creech'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'CCC-5311 MCN'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Nashville'	System	22 Feb 2021 17:18:33



**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'TN'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered '37027'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:51:06
User entered 'US'	System	22 Feb 2021 17:19:12

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	06 Apr 2021 17:34:46
User entered '3'	System	22 Mar 2021 13:34:35
User entered '2'	System	12 Mar 2021 14:51:18
User entered '1'	System	22 Feb 2021 17:19:12

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered		
'USA-US082-2021-MRNA-1273-P301000006'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Yes (Y)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33



**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Yes (Y)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Clarence'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Creech'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'CCC-5311 MCN'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Nashville'	System	22 Feb 2021 17:18:33



**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'TN'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered '37027'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:51:06
User entered 'US'	System	22 Feb 2021 17:19:12

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	06 Apr 2021 17:34:46
User entered '3'	System	22 Mar 2021 13:34:35
User entered '2'	System	12 Mar 2021 14:51:18
User entered '1'	System	22 Feb 2021 17:19:12

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:32:16**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:38:36
User entered '22/Feb/2021 12:19'	System	22 Feb 2021 17:19:12

US3422101

Folder: SAE USA-US082-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:32:16

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:51:06
User entered 'I'	(b) (4), (b) (6)	22 Feb 2021 17:19:12

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered		
'USA-US082-2021-MRNA-1273-P301000006'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Yes (Y)'	System	22 Feb 2021 17:18:33



**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Yes (Y)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Clarence'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Creech'	System	22 Feb 2021 17:18:33



**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'CCC-5311 MCN'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Nashville'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'TN'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered '37027'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:51:06
User entered 'US'	System	22 Feb 2021 17:19:12

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	06 Apr 2021 17:34:46
User entered '3'	System	22 Mar 2021 13:34:35
User entered '2'	System	12 Mar 2021 14:51:18
User entered '1'	System	22 Feb 2021 17:19:12

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:32:16**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:38:36
User entered '12/Mar/2021 09:51'	System	12 Mar 2021 14:51:18

US3422101

Folder: SAE USA-US082-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:32:16

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
User entered 'I'	(b) (4), (b) (6)	12 Mar 2021 14:51:18



**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered		
'USA-US082-2021-MRNA-1273-P301000006'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Yes (Y)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Yes (Y)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33



**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Clarence'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Creech'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'CCC-5311 MCN'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Nashville'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'TN'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered '37027'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:51:06
User entered 'US'	System	22 Feb 2021 17:19:12

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	06 Apr 2021 17:34:46
User entered '3'	System	22 Mar 2021 13:34:35
User entered '2'	System	12 Mar 2021 14:51:18
User entered '1'	System	22 Feb 2021 17:19:12



**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:32:16**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:32:39
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered '22/Mar/2021 06:34'	(b) (4) System	22 Mar 2021 13:34:35

US3422101

Folder: SAE USA-US082-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:32:16

**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 17:32:40
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:34:35

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered		
'USA-US082-2021-MRNA-1273-P301000006'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Yes (Y)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Yes (Y)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33



**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'No (N)'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Clarence'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Creech'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'CCC-5311 MCN'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'Nashville'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered 'TN'	System	22 Feb 2021 17:18:33

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:18:49
User entered '37027'	System	22 Feb 2021 17:18:33



**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Clarence Creech (b) (4)	01 Apr 2021 23:07:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:38:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 14:51:06
User entered 'US'	System	22 Feb 2021 17:19:12

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:32:16**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	06 Apr 2021 17:34:46
User entered '3'	System	22 Mar 2021 13:34:35
User entered '2'	System	12 Mar 2021 14:51:18
User entered '1'	System	22 Feb 2021 17:19:12

**US3422101**

**Folder: SAE USA-US082-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:32:16**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:32:44
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 14:05:27
User entered '06/Apr/2021 13:34'	(b) (4) System	06 Apr 2021 17:34:46

US3422101

Folder: SAE USA-US082-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:32:16

**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 17:32:46
User signature succeeded.	Clarence Creech (b) (4)	08 Apr 2021 14:05:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:34:46