

US3052220 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:56:29

All time stamps listed in this document are displayed in GMT

US3052220

Form: Participant Creation

Data signed: (b) (4) 15 Mar 2021 17:35:45

Generated On: 09 Jun 2021 14:56:29

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[Participant ID](#)

US3052220

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

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US3052220

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	68
Age Units	YEARS
Age (Derived)	68
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Mar 2021 17:36:18

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	14 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 checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Mar 2021 17:36:18

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Mar 2021 17:36:18

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Mar 2021 17:36:18

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Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Condition	ACID REFLUX
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)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Condition	VOCAL CORD CANCER
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	14 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	11:50 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:50
Height ( <i>xxx.x</i> )	175 cm
Weight ( <i>xxx.x</i> )	102 kg
BMI ( <i>xxx.x</i> )	33.30612 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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 17:36:18

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Mar 2021 17:36:18

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

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**Specify** RETIRED

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Mar 2021 17:36:18

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<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>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 186307

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

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)	14 AUG 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:50
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	161 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

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)	14 AUG 2020
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 13:10
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

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) 14 AUG 2020

What was the treatment time? (00:00-23:59) 12:29 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 12:29

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 AUG 2020

Collection time (00:00-23:59)

12:22 (24 HR)

Collection date and time (derived)

14 AUG 2020 12:22

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:14	14 AUG 2020 12:14
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

14 AUG 2020 13:13

PC Open Date & Time

14 AUG 2020 12:49

PC Close Date & Time

14 AUG 2020 15:19

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**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 98.4 °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	14 AUG 2020 17:34
PC Open Date & Time	14 AUG 2020 16:14
PC Close Date & Time	15 AUG 2020 11:59

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:29

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**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

97.9 °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

15 AUG 2020 13:32

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:29

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**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.

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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):

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PC Time Stamp

16 AUG 2020 14:37

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PC Open Date & Time

16 AUG 2020 12:00

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PC Close Date & Time

17 AUG 2020 11:59

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US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:29

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**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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 13:36

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**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

98.3 °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

18 AUG 2020 13:20

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:29

---

**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

98.5 °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

19 AUG 2020 18:58

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:29

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**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

98.0 °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

20 AUG 2020 12:47

---

PC Open Date & Time

20 AUG 2020 12:00

---

PC Close Date & Time

21 AUG 2020 11:59

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US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**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

14 AUG 2020 13:14

PC Open Date & Time

14 AUG 2020 12:49

PC Close Date & Time

14 AUG 2020 15:19

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**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

14 AUG 2020 17:35

PC Open Date & Time

14 AUG 2020 16:14

PC Close Date & Time

15 AUG 2020 11:59

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**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

15 AUG 2020 13:32

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**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

16 AUG 2020 14:30

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**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

17 AUG 2020 13:31

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**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

18 AUG 2020 13:20

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**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

19 AUG 2020 18:59

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**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

20 AUG 2020 12:48

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59



US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**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 ☐

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 13:12
PC Open Date & Time	14 AUG 2020 12:49
PC Close Date & Time	14 AUG 2020 15:19

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**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 ☐

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 17:36
PC Open Date & Time	14 AUG 2020 16:14
PC Close Date & Time	15 AUG 2020 11:59

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**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 ☒

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 13:33
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 14:31
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59



US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**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 ☒

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 13:32
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

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 ☒

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 13:21
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

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

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

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

54 of 2111

EAB) (1725)

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 12:49
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59



US3052220

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052220

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052220

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052220

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052220

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

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

US3052220

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052220

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 17:36:19

Generated On: 09 Jun 2021 14:56:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Mar 2021 17:36:19

Generated On: 09 Jun 2021 14:56:29

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)	17 SEP 2020
Time of assessment (00:00-23:59)	10:52 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 10:52
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG



US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Mar 2021 17:36:19

Generated On: 09 Jun 2021 14:56:29

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	12:34 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 12:34
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3052220

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 17:36:19

Generated On: 09 Jun 2021 14:56:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3052220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Mar 2021 17:36:19

Generated On: 09 Jun 2021 14:56:29

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 17 SEP 2020

What was the treatment time? (00:00-23:59) 11:54 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 11:54

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

US3052220

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Mar 2021 17:36:19

Generated On: 09 Jun 2021 14:56:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 SEP 2020
Collection time (00:00-23:59)	10:25 (24 HR)
Collection date and time (derived)	17 SEP 2020 10:25

US3052220

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Mar 2021 17:36:19

Generated On: 09 Jun 2021 14:56:29

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:27	17 SEP 2020 10:27
Nasopharyngeal Swab 2	No		

US3052220

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 17:36:19

Generated On: 09 Jun 2021 14:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °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 17 SEP 2020 12:36

PC Open Date & Time 17 SEP 2020 12:14

PC Close Date & Time 17 SEP 2020 14:44

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

PC Time Stamp	17 SEP 2020 21:08
PC Open Date & Time	17 SEP 2020 15:39
PC Close Date & Time	18 SEP 2020 11:59



US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**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

18 SEP 2020 12:50

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:29

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**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

97.9 °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

19 SEP 2020 15:42

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:29

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**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

97.5 °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

20 SEP 2020 14:13

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:29

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

21 SEP 2020 14:42

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:29

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**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

22 SEP 2020 16:32

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:29

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**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

98.3 °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

23 SEP 2020 13:47

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PC Open Date & Time

23 SEP 2020 12:00

---

PC Close Date & Time

24 SEP 2020 11:59

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US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**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

17 SEP 2020 12:37

PC Open Date & Time

17 SEP 2020 12:14

PC Close Date & Time

17 SEP 2020 14:44

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**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

17 SEP 2020 21:09

PC Open Date & Time

17 SEP 2020 15:39

PC Close Date & Time

18 SEP 2020 11:59



US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**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

18 SEP 2020 12:51

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**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

19 SEP 2020 15:43

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**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

20 SEP 2020 14:15

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**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

21 SEP 2020 14:43

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**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

22 SEP 2020 16:32

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**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

23 SEP 2020 13:49

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**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 ☐

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 12:38
PC Open Date & Time	17 SEP 2020 12:14
PC Close Date & Time	17 SEP 2020 14:44



US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**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 ☐

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 21:10
PC Open Date & Time	17 SEP 2020 15:39
PC Close Date & Time	18 SEP 2020 11:59

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**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 ☒

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:52
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 15:45
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**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 ☒

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 14:16
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59



US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**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 ☒

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 14:44
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**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 ☒

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 16:34
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**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 ☒

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 13:50
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3052220

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052220

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3052220

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052220

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052220

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052220

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052220

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 17:36:19

Generated On: 09 Jun 2021 14:56:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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

US3052220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Mar 2021 17:36:19

Generated On: 09 Jun 2021 14:56:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 11:05
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3052220

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 17:36:19

Generated On: 09 Jun 2021 14:56:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3052220

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Mar 2021 17:36:19

Generated On: 09 Jun 2021 14:56:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 OCT 2020
Collection time (00:00-23:59)	11:29 (24 HR)
Collection date and time (derived)	15 OCT 2020 11:29



US3052220

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 17:36:19

Generated On: 09 Jun 2021 14:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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

16 OCT 2020 10:48:29

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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 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	21 OCT 2020 10:20:20
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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 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	28 OCT 2020 18:46:08
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 92

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

No ☒

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 NOV 2020 10:09:45

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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 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	19 NOV 2020 09:36:23
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59



US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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

22 NOV 2020 14:50:13

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 16:23:13

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 19:48:06

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 12:51:45

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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

23 DEC 2020 00:08:28

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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

28 DEC 2020 09:46:01

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 11:44:48

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	12 JAN 2021 13:47:15
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59



US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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

18 JAN 2021 13:42:40

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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

24 JAN 2021 21:33:00

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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

01 FEB 2021 10:37:01

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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	07 FEB 2021 23:22:38
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 17:09:24

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 12:01:22

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 14:01:51

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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

09 MAR 2021 16:33:33

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59



US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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

14 MAR 2021 12:51:22

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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

21 MAR 2021 11:32:15

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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

30 MAR 2021 15:07:46

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 20:32:41

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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

12 APR 2021 09:47:35

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 15:01:10

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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

Date and time of submission

26 APR 2021 14:00:11

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 12:04:03

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59



US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 271

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAY 2021 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUN 2021 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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 <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"/>

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUN 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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"/>

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 JUL 2021 23:59



US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 JUL 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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°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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 AUG 2021 23:59



US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 SEP 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 SEP 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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"/>

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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="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"/>

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 SEP 2021 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 OCT 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 OCT 2021 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 446

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 NOV 2021 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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="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"/>

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59



US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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"/>

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2021 23:59



US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 DEC 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JAN 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59



US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 FEB 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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="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"/>

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 APR 2022 23:59



US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 APR 2022 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 614

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 APR 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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"/>

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 APR 2022 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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29 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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="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"/>

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 JUN 2022 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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26 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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="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"/>

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 JUL 2022 23:59

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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10 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUL 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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="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"/>

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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31 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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="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"/>

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59
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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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="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"/>

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 SEP 2022 23:59



US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 SEP 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2022 23:59
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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	02 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2022 23:59
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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

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

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[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

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US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

DAY 796

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

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

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

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

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

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

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 ☐

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2022 23:59



US3052220

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:56:29

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 14:02:11

US3052220

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052220

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052220

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052220

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052220

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 16:28:23

Generated On: 09 Jun 2021 14:56:29

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

US3052220

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:42:49

Generated On: 09 Jun 2021 14:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052220

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3052220

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052220

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 17:36:19

Generated On: 09 Jun 2021 14:56:29

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

Visit date (dd MMM yyyy)	25 FEB 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3052220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 17:33:06

Generated On: 09 Jun 2021 14:56:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	25 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	11:53 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 11:53
Temperature ( <i>xxx.x</i> )	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	70 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3052220

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 17:36:19

Generated On: 09 Jun 2021 14:56:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3052220

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 17:33:06

Generated On: 09 Jun 2021 14:56:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 FEB 2021
Collection time (00:00-23:59)	13:45 (24 HR)
Collection date and time (derived)	25 FEB 2021 13:45

US3052220

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 17:36:19

Generated On: 09 Jun 2021 14:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052220

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 15:25:17

Generated On: 09 Jun 2021 14:56:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052220

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 15:25:17

Generated On: 09 Jun 2021 14:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3052220**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

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*

**US3052220**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3052220

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:56:29

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

**US3052220**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 14:56:29**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3052220

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

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

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

Visit date (dd MMM yyyy)	26 JAN 2021
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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
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US3052220

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

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Date of updated informed consent ( <i>dd MMM yyyy</i> )	26 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	26 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3052220

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Height	175 cm
Weight	102 kg
BMI (xxx.x)	33.30612

US3052220

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Height	175 cm
Weight	102 kg
BMI (xxx.x)	33.30612
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)	26 JAN 2021
Time of assessment (00:00-23:59)	14:27 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 14:27
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)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG



US3052220

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Height	175 cm
Weight	102 kg
BMI (xxx.x)	33.30612
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)	26 JAN 2021
Time of assessment (00:00-23:59)	16:15 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 16:15
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)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3052220

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

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 JAN 2021

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

US3052220

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

Form: Exposure

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 JAN 2021

What was the treatment time? (00:00-23:59) 15:40 (24 HR)

Treatment Date and Time (derived) 26 JAN 2021 15:40

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

US3052220

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00-23:59)

15:32 (24 HR)

Collection date and time (derived)

26 JAN 2021 15:32

US3052220

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 JAN 2021
Collection time (00:00 - 23:59)	15:34
Collection Date and Time (derived)	26 JAN 2021 15:34

US3052220

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

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052220

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3052220

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

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



US3052220

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 17:35:46

Generated On: 09 Jun 2021 14:56:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3052220

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Mar 2021 17:35:46

Generated On: 09 Jun 2021 14:56:29

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 FEB 2021
Time of assessment (00:00-23:59)	11:53 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 11:53
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3052220

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Mar 2021 17:35:46

Generated On: 09 Jun 2021 14:56:29

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 FEB 2021
Time of assessment (00:00-23:59)	13:02 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 13:02
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3052220

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 17:35:46

Generated On: 09 Jun 2021 14:56:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3052220

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 15 Mar 2021 17:35:45

Generated On: 09 Jun 2021 14:56:29

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 25 FEB 2021

What was the treatment time? (00:00-23:59) 12:27 (24 HR)

Treatment Date and Time (derived) 25 FEB 2021 12:27

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

US3052220

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 17:35:45

Generated On: 09 Jun 2021 14:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052220

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:42:49

Generated On: 09 Jun 2021 14:56:29

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

MISSED

If Contact Not Made, please provide Comments

US3052220

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 17:36:18

Generated On: 09 Jun 2021 14:56:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3052220

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 17:33:06

Generated On: 09 Jun 2021 14:56:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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	OLD57

US3052220

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 17:33:06

Generated On: 09 Jun 2021 14:56:29

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) \_\_\_\_\_

US3052220

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 17:33:06

Generated On: 09 Jun 2021 14:56:29

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.*

US3052220

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 17:33:06

Generated On: 09 Jun 2021 14:56:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 MAR 2021
Collection time (00:00-23:59)	12:06 (24 HR)
Collection date and time (derived)	23 MAR 2021 12:06

US3052220

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 17:35:45

Generated On: 09 Jun 2021 14:56:29

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3052220

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

AEID

Adverse event

LEFT SIDED LYMPHADENITIS  
OF THE SALIVARY GLAND

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)

01 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3052220

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

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

US3052220

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

---

PARTICIPANT HAD 2ND  
INJECTION 17-SEP-2020.  
PATIENT REPORTED HE HAD  
TO BE TREATED FOR AN  
INFECTED SALIVA GLAND, DUE  
TO LARGE SWELLING OF LEFT  
NECK. PATIENT WAS PLACED  
ON UNKNOWN PO ANTIBIOTIC  
FROM 03-OCT-2020 THRU  
13-OCT-2020. PATIENT ALSO  
HAD EYEBROW LIFT SURGERY  
BETWEEN 1ST AND SECOND  
INJECTION.

---

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)	

---

---



US3052220

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

AEID	USA-US117-2021-MRNA-1273-P30 1000002
Adverse event	THYROID CANCER
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)	22 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" 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	True
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"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

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

US3052220

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

---

PARTICIPANT HAD 2ND  
INJECTION 17-SEP-2020.  
PATIENT REPORTED HE HAD  
TO BE TREATED FOR AN  
INFECTED SALIVA GLAND, DUE  
TO LARGE SWELLING OF LEFT  
NECK. PATIENT WAS PLACED  
ON UNKNOWN PO ANTIBIOTIC  
FROM 03-OCT-2020 THRU  
13-OCT-2020. THROUGH AN  
ULTRASOUND TO CHECK THE  
GLAND NODULES WERE  
DISCOVERED ON THE  
THYROID. BIOPSY DONE WITH  
A DIAGNOSIS OF THYROID  
CANCER. THE THYROID WAS  
REMOVED AND SUBJECT PUT  
ON SYNTHROID AS WELL AS  
CURRENTLY RECEIVING  
RADIOTHERAPY .

---

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)	

---

---

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Mar 2021 17:35:45

Generated On: 09 Jun 2021 14:56:29

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

Yes ☒

No ☐

---

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

---

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

Name of Medication EFFEXOR

Prophylaxis Yes ☒  
No ☐

Indication UNKNOWN

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

Name of Medication CLONAZEPAN

Prophylaxis Yes ☒  
No ☐

Indication UNKNOWN

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☒  
No ☐

Indication UNKNOWN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

Name of Medication ALPRAZOLAM

Prophylaxis Yes ☒  
No ☐

Indication UNKNOWN

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

Name of Medication TEMAZEPAM

Prophylaxis Yes ☒  
No ☐

Indication UNKNOWN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

Name of Medication	FLU SHOT
Prophylaxis	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Indication	SEASONAL VACCINE
------------	------------------

Dose per administration	1
-------------------------	---

Dose unit	mg <input type="radio"/>
	ug <input type="radio"/>
	mL <input type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input checked="" type="radio"/>

If dose unit is Other, specify	INJECTION
--------------------------------	-----------

Frequency	once daily <input type="radio"/>
	twice daily <input type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input checked="" type="radio"/>
	unknown <input type="radio"/>
	other <input type="radio"/>

If frequency is Other, specify	
--------------------------------	--

Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

	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)		08 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		08 SEP 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"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

Name of Medication AUGMENTIN

Prophylaxis Yes ☐  
No ☒

Indication LEFT-SIDED LYMPHADENITIS  
OF THE SALIVARY GLAND

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

	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)	3 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

Name of Medication SYNTHROID

Prophylaxis Yes ☐  
No ☒

Indication THYROID CANCER

Dose per administration 168

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3052220

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Mar 2021 17:35:45

Generated On: 09 Jun 2021 14:56:29

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3052220

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Apr 2021 13:49:57

Generated On: 09 Jun 2021 14:56:29

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
1 SEP 2020	BROW LIFT	Other	COSMETIC
22 OCT 2020	BIOPSY OF NODULE IN THYROID	Diagnostic	
04 JAN 2021	THYROIDECTOMY	Adverse Event	
12 FEB 2021	RADIOTHERAPY	Adverse Event	
22 OCT 2020	ULTRASOUND	Adverse Event	

US3052220

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:56:29

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

US3052220

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:56:29

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 ☐



US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 23 Apr 2021 13:49:58

Generated On: 09 Jun 2021 14:56:29

SAEID	USA-US117-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Apr 2021 13:49:58

Generated On: 09 Jun 2021 14:56:29

SAEID	USA-US117-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	01/MAR/2021 12:36
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

US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Apr 2021 13:49:58

Generated On: 09 Jun 2021 14:56:29

SAEID	USA-US117-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	11/MAR/2021 11:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Apr 2021 13:49:58

Generated On: 09 Jun 2021 14:56:29

SAEID	USA-US117-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	14/APR/2021 08:34
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

US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Apr 2021 13:49:58

Generated On: 09 Jun 2021 14:56:29

SAEID	USA-US117-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/APR/2021 08:09
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

US3052220 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

**US3052220**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 14:56:29**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 17:44:27
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'US3052220'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:04:28

**US3052220**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:11:07
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:32:49



**US3052220**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:11:07
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:04:29

**US3052220**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	05 Nov 2020 16:11:07
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Aug 2020 16:32:49
	Nicole Davis (b) (4)	
	(b) (4)	

**US3052220**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered 'SCRN'	System	14 Aug 2020 16:32:49

US3052220

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:29

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	05 Nov 2020 16:47:24
User entered (b) (6) 1952'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:04:30

**US3052220**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:29**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:47:24
User entered '68'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:33:15

**US3052220**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:29**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered 'YEARS'	System	14 Aug 2020 16:33:15

**US3052220**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:29**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '68'	System	14 Aug 2020 16:33:27

**US3052220**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:29**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	05 Nov 2020 16:47:24
User entered 'Male (M)'	Nicole Davis (b) (4)	14 Aug 2020 16:33:15



US3052220

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:56:29

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Query 'Ethnicity blank in source. Please review and reconcile.' canceled (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:57:12 05 Nov 2020 16:57:10
User opened query 'Ethnicity blank in source. Please review and reconcile.' (Site from CRA). DataPoint Un-verified.		05 Nov 2020 16:49:37 05 Nov 2020 16:47:26
DataPoint Verified.		05 Nov 2020 16:47:24
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:33:15

**US3052220**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:29**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:47:24
User entered 'I'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:33:15

**US3052220**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:29**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:47:24
User entered '0'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:33:15

**US3052220**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:29**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:47:24
User entered '0'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:33:15

**US3052220**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:29**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:47:24
User entered '0'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:33:15

**US3052220**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:29**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:47:24
User entered '0'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:33:15

**US3052220**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:29**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:47:24
User entered '0'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:33:15

**US3052220**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:29**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:47:24
User entered empty.	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:33:15



**US3052220**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:29**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:47:24
User entered '0'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:33:15

**US3052220**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:29**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:47:24
User entered '0'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:33:15

US3052220

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:29

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:50:58
User entered '14 Aug 2020'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:33:27

**US3052220**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered 'Aug 2020'	System	14 Aug 2020 16:33:27

**US3052220**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '2020'	System	14 Aug 2020 16:33:27

US3052220

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:29

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:50:58
User entered 'Amendment 2 (2)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:33:27

US3052220

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:50:58
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:33:27

**US3052220**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:56:29**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:50:58
User entered empty.	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:33:27



**US3052220**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:56:29**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:50:58
User entered empty.	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:33:27

**US3052220**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:56:29**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:50:58
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:33:27

**US3052220**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:56:29**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:50:58
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:04:29

US3052220

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:56:29

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered 'I'	System	14 Aug 2020 16:33:33

US3052220

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:50:43
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:33:33

US3052220

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:56:29

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:52:52
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:04:05

US3052220

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:45
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:06:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:06:23
Data point term sent to Coder	System	19 Aug 2020 19:05:27
User entered 'Sleep Apnea'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:04:38

US3052220

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:54:45
User entered 'un UNK 2010' reason for change:	amy sheets (b) (4)	19 Aug 2020 19:06:31
Data Entry Error	(b) (4)	
User entered '14 Aug 2020'	amy sheets (b) (4)	19 Aug 2020 19:04:38
	(b) (4)	



**US3052220**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	05 Nov 2020 16:54:45
User entered '0'	amy sheets (b) (4)	19 Aug 2020 19:04:38

US3052220

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:45
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:04:38

US3052220

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:45
User entered empty.	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:04:38

**US3052220**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:45
User entered '0'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:04:38

**US3052220**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered 'Jan 2010'	System	19 Aug 2020 19:06:31
User entered 'Aug 2020'	System	19 Aug 2020 19:04:38

**US3052220**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '2010'	System	19 Aug 2020 19:06:31
User entered '2020'	System	19 Aug 2020 19:04:38

**US3052220**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered empty.	System	19 Aug 2020 19:04:38

**US3052220**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered empty.	System	19 Aug 2020 19:04:38



US3052220

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:45
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:07:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:07:26
Data point term sent to Coder	System	19 Aug 2020 19:06:29
User entered 'Acid Reflux'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:05:43

**US3052220**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:45
User entered 'un UNK 1990'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:05:43

US3052220

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	05 Nov 2020 16:54:45
User entered '0'	amy sheets (b) (4)	19 Aug 2020 19:05:43

**US3052220**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:56:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:45
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:05:43

**US3052220**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:45
User entered empty.	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:05:43

**US3052220**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:56:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:45
User entered '0'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:05:43

**US3052220**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered 'Jan 1990'	System	19 Aug 2020 19:05:43

**US3052220**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '1990'	System	19 Aug 2020 19:05:43



**US3052220**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered empty.	System	19 Aug 2020 19:05:43

**US3052220**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered empty.	System	19 Aug 2020 19:05:43

US3052220

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:45
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Respiratory and mediastinal neoplasms malignant and unspecified, HLT: Laryngeal neoplasms malignant, PT: Laryngeal cancer, LLT: Carcinoma vocal cord - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 05:52:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 05:52:18
Data point term sent to Coder	System	19 Aug 2020 19:06:30
User entered 'Vocal Cord Cancer'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:06:07

US3052220

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	05 Nov 2020 16:54:45
User entered 'un UNK 1990'	(b) (4), (b) (6)	19 Aug 2020 19:06:07
	amy sheets (b) (4)	
	(b) (4)	

US3052220

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:45
User entered '0'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:06:07

**US3052220**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:56:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:45
User entered 'No (N)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:06:07

**US3052220**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:54:45
User entered 'un UNK 1990'	amy sheets (b) (4)	19 Aug 2020 19:06:07
	(b) (4)	

**US3052220**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:56:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	05 Nov 2020 16:54:45
User entered '0'	amy sheets (b) (4)	19 Aug 2020 19:06:07



**US3052220**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered 'Jan 1990'	System	19 Aug 2020 19:06:07

**US3052220**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '1990'	System	19 Aug 2020 19:06:07

**US3052220**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered 'Jan 1990'	System	19 Aug 2020 19:06:07

**US3052220**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '1990'	System	19 Aug 2020 19:06:07

US3052220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:57:26
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:08:34

US3052220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	05 Nov 2020 16:57:26
User entered '14 Aug 2020'	amy sheets (b) (4)	19 Aug 2020 19:08:34

US3052220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:57:26
User entered '11:50'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:08:34

**US3052220**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '14 Aug 2020 11:50'	System	19 Aug 2020 19:08:34



US3052220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:57:26
User entered '175' cm	amy sheets (b) (4)	19 Aug 2020 19:08:34
DataPoint set to visible.	(b) (4) System	14 Aug 2020 16:33:33

US3052220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:57:26
User entered '102' kg	amy sheets (b) (4)	19 Aug 2020 19:08:34
DataPoint set to visible.	(b) (4) System	14 Aug 2020 16:33:33

**US3052220**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Amendment Manager: User entered '33.30612'	System	16 Sep 2020 23:57:17
User entered '33.3'	System	19 Aug 2020 19:08:34
DataPoint set to visible.	System	14 Aug 2020 16:33:33

**US3052220**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered 'kg/m2'	System	19 Aug 2020 19:08:34
DataPoint set to visible.	System	14 Aug 2020 16:33:33

US3052220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:57:26
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).		22 Oct 2020 10:10:21
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' answered with 'screening and day 1 same day. updated' (Site from DM).	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:13:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:13:23
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded for TEMPERATURE, the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 09:24:56
User entered '98.4' F	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:08:34

US3052220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:57:26
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:13:23
User entered 'Oral (Oral)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:08:34

US3052220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:57:26
User entered empty.	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:08:34

US3052220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:57:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:13:23
User entered '77'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:08:34



**US3052220**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered 'bpm'	System	19 Aug 2020 19:08:34

US3052220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:57:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:13:23
User entered '14'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:08:34

US3052220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered 'breaths/min'	System	19 Aug 2020 19:08:34

US3052220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:57:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:13:23
User entered '161'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:08:34

**US3052220**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered 'mmHg'	System	19 Aug 2020 19:08:34

US3052220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:57:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:13:23
User entered '91'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:08:34

**US3052220**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered 'mmHg'	System	19 Aug 2020 19:08:34

US3052220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48



US3052220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48

US3052220

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:57:36
User entered 'Yes (Y)'	amy sheets (b) (4)	19 Aug 2020 19:09:00
	(b) (4)	

US3052220

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	05 Nov 2020 16:57:36
User entered '14 Aug 2020'	amy sheets (b) (4)	19 Aug 2020 19:09:00

US3052220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:33
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:11

US3052220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:33
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:11

US3052220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:33
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:11

US3052220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:33
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:11

US3052220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:33
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:11



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:33
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:11

US3052220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:33
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:11

US3052220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:33
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:11

US3052220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:33
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:11

US3052220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:33
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:11

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:33
User entered 'No (N)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:11

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:33
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:11

US3052220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:33
User entered 'retired'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:11



US3052220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '0'	Nicole Davis (b) (4)	14 Aug 2020 16:34:11

US3052220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:33
User entered '0'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:11

US3052220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:33
User entered '0'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:11

US3052220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:33
User entered '0'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:11

US3052220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:33
User entered '0'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:11

US3052220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:33
User entered 'I'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:11

US3052220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '0'	(b) (4) Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:11

US3052220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	05 Nov 2020 16:55:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:55:33
	(b) (4)	
	Nicole Davis (b) (4)	14 Aug 2020 16:34:11
	(b) (4)	



**US3052220**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:57:50
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:21

**US3052220**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:57:50
User entered '14 Aug 2020'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:21

US3052220

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:56:29

[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 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:57:50
User entered 'Clinic (Clinic)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:21

**US3052220**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'VISIT1'	System	14 Aug 2020 16:34:21

US3052220

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:59:12
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:04:50

US3052220

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:29

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:59:12
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:33:14
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:33:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 16:04:50
User entered '186307' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:04:50

US3052220

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:59:12
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:04:50

US3052220

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:29

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 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:59:12
User entered 'No (N)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:10:29



US3052220

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:29

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 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:59:12
User entered 'No (N)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:10:29

US3052220

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:59:12
User entered 'No (N)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:10:29

US3052220

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:29

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:59:12
User entered 'No (N)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:10:29

US3052220

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:29

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:59:12
User entered 'No (N)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:10:29

**US3052220**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:59:12
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:13:57
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:21:02
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:18:08

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	05 Nov 2020 17:04:28
User closed query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be completed only at Screening and marked as 'ND' for Visit 1 Day 1. Note that when 'ND' is recorded, the units should not remain. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 17:20:43
Query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be completed only at Screening and marked as 'ND' for Visit 1 Day 1. Note that when 'ND' is recorded, the units should not remain. Please review and update as appropriate.' answered with 'screening and day 1 same day. updated' (Site from DM).	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:14:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:14:13
User opened query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be completed only at Screening and marked as 'ND' for Visit 1 Day 1. Note that when 'ND' is recorded, the units should not remain. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 13:35:44
User entered '175' cm	amy sheets (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:14:13
User entered '102' kg	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User closed query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be completed only at Screening and marked as 'ND' for Visit 1 Day 1. Note that when 'ND' is recorded, the units should not remain. Please review and update as appropriate.' (Site from DM).		22 Oct 2020 17:20:43
Query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be completed only at Screening and marked as 'ND' for Visit 1 Day 1. Note that when 'ND' is recorded, the units should not remain. Please review and update as appropriate.' answered with 'screening and day 1 same day. updated' (Site from DM).	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:14:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:14:13
User opened query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be completed only at Screening and marked as 'ND' for Visit 1 Day 1. Note that when 'ND' is recorded, the units should not remain. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 13:35:44
User entered '175' cm	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44



US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:14:13
User entered '102' kg	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User accepted default value 'Pre-Dose (PREDOSE)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered '14 Aug 2020'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered '11:50'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

**US3052220**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered '14 Aug 2020 11:50'	System	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered '98.4' F	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered 'Oral (Oral)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44



US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered empty.	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered '77'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'bpm'	System	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered '14'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'breaths/min'	System	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
Amendment Manager: User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:57:17
Amendment Manager: Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	16 Sep 2020 23:57:17
Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	16 Sep 2020 23:57:17
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	19 Aug 2020 19:12:44
User entered '161'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'mmHg'	System	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered '91'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44



US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'mmHg'	System	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User closed query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be completed only at Screening and marked as 'ND' for Visit 1 Day 1. Note that when 'ND' is recorded, the units should not remain. Please review and update as appropriate.' (Site from DM).		22 Oct 2020 17:20:43
Query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be completed only at Screening and marked as 'ND' for Visit 1 Day 1. Note that when 'ND' is recorded, the units should not remain. Please review and update as appropriate.' answered with 'screening and day 1 same day. updated' (Site from DM).	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:14:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:14:13
User opened query 'Per CDM: Per pages 15-16 of the CCGs, if Screening and Visit 1 Day 1 occur on the same day, Height and Weight are to be completed only at Screening and marked as 'ND' for Visit 1 Day 1. Note that when 'ND' is recorded, the units should not remain. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 13:35:44
User entered '175' cm	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:14:13
User entered '102' kg	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User accepted default value 'Post-Dose (POSTDOSE)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered '14 Aug 2020'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 04:33:11
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		19 Aug 2020 19:12:44
User entered '13:10'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

**US3052220**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered '14 Aug 2020 13:10'	System	19 Aug 2020 19:12:44



US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered '98.2' F	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered 'Oral (Oral)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered empty.	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered '76'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'bpm'	System	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered '22'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'breaths/min'	System	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered '132'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'mmHg'	System	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:28
User entered '84'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'mmHg'	System	19 Aug 2020 19:12:44

US3052220

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:34
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:15:06
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:33

US3052220

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:34
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:15:06
User entered '14 Aug 2020'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:34:33

US3052220

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:40
User entered 'Yes (Y)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:37:22

US3052220

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:40
User entered empty.	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:37:22

US3052220

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

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 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:40
User entered empty.	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:37:22



US3052220

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 16:37:22

US3052220

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:40
User entered '14 Aug 2020'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:37:22

US3052220

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:40
User entered '12:29'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:37:22

**US3052220**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered '14 Aug 2020 12:29'	System	14 Aug 2020 16:37:22

US3052220

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:40
User entered 'Left Arm (LEFT ARM)'	Nicole Davis (b) (4) (b) (4)	14 Aug 2020 16:37:22

US3052220

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:04:40
User entered 'ONCE'	System	14 Aug 2020 16:37:22

US3052220

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 16:37:22

US3052220

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:08:08
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:13:12



US3052220

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:08:08
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 14AUG2020; however, it has not been received by GCL. Please clarify.' (Site from DM).		05 Nov 2020 04:29:16
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 14AUG2020; however, it has not been received by GCL. Please clarify.' answered with 'collection was shipped' (Site from DM).	Avia McClain-Stocker (b) (4)	21 Oct 2020 15:14:49
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 14AUG2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 17:23:47
User entered '14 Aug 2020'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:13:12

US3052220

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:08:08
User entered '12:22'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:13:12

**US3052220**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered '14 Aug 2020 12:22'	System	19 Aug 2020 19:13:12

US3052220

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:56:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	05 Nov 2020 17:08:59
User entered '14 Aug 2020'	(b) (4), (b) (6)	
	amy sheets (b) (4)	19 Aug 2020 19:13:48
	(b) (4)	

US3052220

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:13:48

US3052220

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:08:59
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:13:48

US3052220

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:08:59
User entered '12:14'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:13:48

**US3052220**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered '14 Aug 2020 12:14'	System	19 Aug 2020 19:13:48



US3052220

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:13:48

US3052220

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:08:59
User entered 'No (N)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:13:48

US3052220

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:08:59
User entered empty.	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:13:48

**US3052220**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered empty.	System	19 Aug 2020 19:13:48

US3052220

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:09:09
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:13:56

**US3052220**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'I'	System	19 Aug 2020 19:13:56

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T13:13:03', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '34f42110-18d2-440f-8338-24cce2e15bba'	System	14 Aug 2020 17:13:33
User entered 'Yes (Y)'	System	14 Aug 2020 17:13:33



US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T13:13:18', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '34f42110-18d2-440f-8338-24cce2e15bba'	System	14 Aug 2020 17:13:33
User entered '98.2'	System	14 Aug 2020 17:13:33

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T13:13:23', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '34f42110-18d2-440f-8338-24cce2e15bba'	System	14 Aug 2020 17:13:33
User entered 'No (N)'	System	14 Aug 2020 17:13:33

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T13:13:30', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '34f42110-18d2-440f-8338-24cce2e15bba'	System	14 Aug 2020 17:13:33
User entered '14 Aug 2020 13:13'	System	14 Aug 2020 17:13:33

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '14 Aug 2020 12:49'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '14 Aug 2020 15:19'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T17:33:47', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '6daefda2-8dc5-4824-9615-02ef0968665b'	System	14 Aug 2020 21:34:30
User entered 'Yes (Y)'	System	14 Aug 2020 21:34:30

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T17:34:01', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '6daefda2-8dc5-4824-9615-02ef0968665b'	System	14 Aug 2020 21:34:30
User entered '98.4'	System	14 Aug 2020 21:34:30



US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T17:34:07', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '6daefda2-8dc5-4824-9615-02ef0968665b'	System	14 Aug 2020 21:34:30
User entered 'No (N)'	System	14 Aug 2020 21:34:30

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T17:34:24', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '6daefda2-8dc5-4824-9615-02ef0968665b'	System	14 Aug 2020 21:34:30
User entered '14 Aug 2020 17:34'	System	14 Aug 2020 21:34:30

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '14 Aug 2020 16:14'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 2'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-15T13:31:18', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '11e2ba65-1f63-498c-b460-dbf878f6176a'	System	15 Aug 2020 17:32:10
User entered 'Yes (Y)'	System	15 Aug 2020 17:32:10

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-15T13:31:48', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '11e2ba65-1f63-498c-b460-dbf878f6176a'	System	15 Aug 2020 17:32:10
User entered '97.9'	System	15 Aug 2020 17:32:10

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-15T13:31:54', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '11e2ba65-1f63-498c-b460-dbf878f6176a'	System	15 Aug 2020 17:32:10
User entered 'No (N)'	System	15 Aug 2020 17:32:10



US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-15T13:32:07', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '11e2ba65-1f63-498c-b460-dbf878f6176a'	System	15 Aug 2020 17:32:10
User entered '15 Aug 2020 13:32'	System	15 Aug 2020 17:32:10

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 3'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-16T14:37:08', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'af462eb9-41d5-4b94-ad18-3aa4d1a28c94'	System	16 Aug 2020 18:37:35
User entered 'Yes (Y)'	System	16 Aug 2020 18:37:35

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-16T14:37:17', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'af462eb9-41d5-4b94-ad18-3aa4d1a28c94'	System	16 Aug 2020 18:37:35
User entered '97.7'	System	16 Aug 2020 18:37:35

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-16T14:37:23', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'af462eb9-41d5-4b94-ad18-3aa4d1a28c94'	System	16 Aug 2020 18:37:35
User entered 'No (N)'	System	16 Aug 2020 18:37:35

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-16T14:37:32', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'af462eb9-41d5-4b94-ad18-3aa4d1a28c94'	System	16 Aug 2020 18:37:35
User entered '16 Aug 2020 14:37'	System	16 Aug 2020 18:37:35



US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 4'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-17T13:35:21', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '1163b1cd-492e-4a0a-8ac6-b73d6c2b4096'	System	17 Aug 2020 17:36:37
User entered 'Yes (Y)'	System	17 Aug 2020 17:36:37

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-17T13:36:25', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '1163b1cd-492e-4a0a-8ac6-b73d6c2b4096'	System	17 Aug 2020 17:36:37
User entered '97.6'	System	17 Aug 2020 17:36:37

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-17T13:36:29', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '1163b1cd-492e-4a0a-8ac6-b73d6c2b4096'	System	17 Aug 2020 17:36:37
User entered 'No (N)'	System	17 Aug 2020 17:36:37

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-17T13:36:37', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '1163b1cd-492e-4a0a-8ac6-b73d6c2b4096'	System	17 Aug 2020 17:36:37
User entered '17 Aug 2020 13:36'	System	17 Aug 2020 17:36:37

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 16:37:22



**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 5'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-18T13:20:23', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '6e0381e5-24eb-4fbd-8282-9b014217504d'	System	18 Aug 2020 17:20:48
User entered 'Yes (Y)'	System	18 Aug 2020 17:20:48

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-18T13:20:34', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '6e0381e5-24eb-4fbd-8282-9b014217504d'	System	18 Aug 2020 17:20:48
User entered '98.3'	System	18 Aug 2020 17:20:48

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-18T13:20:38', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '6e0381e5-24eb-4fbd-8282-9b014217504d'	System	18 Aug 2020 17:20:48
User entered 'No (N)'	System	18 Aug 2020 17:20:48

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-18T13:20:48', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '6e0381e5-24eb-4fbd-8282-9b014217504d'	System	18 Aug 2020 17:20:48
User entered '18 Aug 2020 13:20'	System	18 Aug 2020 17:20:48

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 16:37:22



US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 6'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-19T18:53:51', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '30e58d35-d2ef-43f6-a0a0-a10d85386680'	System	19 Aug 2020 22:58:31
User entered 'Yes (Y)'	System	19 Aug 2020 22:58:31

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-19T18:58:12', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '30e58d35-d2ef-43f6-a0a0-a10d85386680'	System	19 Aug 2020 22:58:31
User entered '98.5'	System	19 Aug 2020 22:58:31

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-19T18:58:16', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '30e58d35-d2ef-43f6-a0a0-a10d85386680'	System	19 Aug 2020 22:58:31
User entered 'No (N)'	System	19 Aug 2020 22:58:31

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-19T18:58:33', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '30e58d35-d2ef-43f6-a0a0-a10d85386680'	System	19 Aug 2020 22:58:31
User entered '19 Aug 2020 18:58'	System	19 Aug 2020 22:58:31

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 7'	System	14 Aug 2020 16:37:22



US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-20T12:42:44', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5757969b-67ca-461c-9eca-89f9d2d11977'	System	20 Aug 2020 16:47:33
User entered 'Yes (Y)'	System	20 Aug 2020 16:47:33

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-20T12:46:49', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5757969b-67ca-461c-9eca-89f9d2d11977'	System	20 Aug 2020 16:47:33
User entered '98.0'	System	20 Aug 2020 16:47:33

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-20T12:46:56', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5757969b-67ca-461c-9eca-89f9d2d11977'	System	20 Aug 2020 16:47:33
User entered 'No (N)'	System	20 Aug 2020 16:47:33

US3052220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-20T12:47:36', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5757969b-67ca-461c-9eca-89f9d2d11977'	System	20 Aug 2020 16:47:33
User entered '20 Aug 2020 12:47'	System	20 Aug 2020 16:47:33

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T13:13:37', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'fb57ec94-1b13-4aa0-b3c5-995847d10e67'	System	14 Aug 2020 17:14:05
User entered 'None (1)'	System	14 Aug 2020 17:14:05



US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T13:13:47', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'fb57ec94-1b13-4aa0-b3c5-995847d10e67'	System	14 Aug 2020 17:14:05
User entered 'No (N)'	System	14 Aug 2020 17:14:05

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T13:13:53', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'fb57ec94-1b13-4aa0-b3c5-995847d10e67'	System	14 Aug 2020 17:14:05
User entered 'No (N)'	System	14 Aug 2020 17:14:05

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T13:13:59', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'fb57ec94-1b13-4aa0-b3c5-995847d10e67'	System	14 Aug 2020 17:14:05
User entered 'None (1)'	System	14 Aug 2020 17:14:05

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T13:14:02', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'fb57ec94-1b13-4aa0-b3c5-995847d10e67'	System	14 Aug 2020 17:14:05
User entered '14 Aug 2020 13:14'	System	14 Aug 2020 17:14:05

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '14 Aug 2020 12:49'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '14 Aug 2020 15:19'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T17:34:35', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3b664b44-9411-4546-a578-7d278e1b7783'	System	14 Aug 2020 21:35:21
User entered 'None (1)'	System	14 Aug 2020 21:35:21



US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T17:34:39', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3b664b44-9411-4546-a578-7d278e1b7783'	System	14 Aug 2020 21:35:21
User entered 'No (N)'	System	14 Aug 2020 21:35:21

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T17:34:43', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3b664b44-9411-4546-a578-7d278e1b7783'	System	14 Aug 2020 21:35:21
User entered 'No (N)'	System	14 Aug 2020 21:35:21

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T17:34:59', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3b664b44-9411-4546-a578-7d278e1b7783'	System	14 Aug 2020 21:35:21
User entered 'None (1)'	System	14 Aug 2020 21:35:21

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T17:35:17', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3b664b44-9411-4546-a578-7d278e1b7783'	System	14 Aug 2020 21:35:21
User entered '14 Aug 2020 17:35'	System	14 Aug 2020 21:35:21

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '14 Aug 2020 16:14'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 2'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-15T13:32:16', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '64926714-5c29-4134-acf8-07b12dea9ae7'	System	15 Aug 2020 17:32:51
User entered 'None (1)'	System	15 Aug 2020 17:32:51



US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-15T13:32:20', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '64926714-5c29-4134-acf8-07b12dea9ae7'	System	15 Aug 2020 17:32:51
User entered 'No (N)'	System	15 Aug 2020 17:32:51

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-15T13:32:26', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '64926714-5c29-4134-acf8-07b12dea9ae7'	System	15 Aug 2020 17:32:51
User entered 'No (N)'	System	15 Aug 2020 17:32:51

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-15T13:32:39', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '64926714-5c29-4134-acf8-07b12dea9ae7'	System	15 Aug 2020 17:32:51
User entered 'None (1)'	System	15 Aug 2020 17:32:51

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-15T13:32:49', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '64926714-5c29-4134-acf8-07b12dea9ae7'	System	15 Aug 2020 17:32:51
User entered '15 Aug 2020 13:32'	System	15 Aug 2020 17:32:51

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 3'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-16T14:29:10', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '87fa29f2-8851-4eb9-ba1f-9a5232a075ea'	System	16 Aug 2020 18:30:08
User entered 'None (1)'	System	16 Aug 2020 18:30:08



US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-16T14:29:18', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '87fa29f2-8851-4eb9-ba1f-9a5232a075ea'	System	16 Aug 2020 18:30:08
User entered 'No (N)'	System	16 Aug 2020 18:30:08

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-16T14:29:36', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '87fa29f2-8851-4eb9-ba1f-9a5232a075ea'	System	16 Aug 2020 18:30:08
User entered 'No (N)'	System	16 Aug 2020 18:30:08

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-16T14:29:48', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '87fa29f2-8851-4eb9-ba1f-9a5232a075ea'	System	16 Aug 2020 18:30:08
User entered 'None (1)'	System	16 Aug 2020 18:30:08

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-16T14:30:05', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '87fa29f2-8851-4eb9-ba1f-9a5232a075ea'	System	16 Aug 2020 18:30:08
User entered '16 Aug 2020 14:30'	System	16 Aug 2020 18:30:08

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 4'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-17T13:30:12', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'c051947a-3b23-4a91-a36d-f55b6d3ac3b5'	System	17 Aug 2020 17:31:07
User entered 'None (1)'	System	17 Aug 2020 17:31:07



US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-17T13:30:17', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'c051947a-3b23-4a91-a36d-f55b6d3ac3b5'	System	17 Aug 2020 17:31:07
User entered 'No (N)'	System	17 Aug 2020 17:31:07

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-17T13:30:21', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'c051947a-3b23-4a91-a36d-f55b6d3ac3b5'	System	17 Aug 2020 17:31:07
User entered 'No (N)'	System	17 Aug 2020 17:31:07

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-17T13:30:27', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'c051947a-3b23-4a91-a36d-f55b6d3ac3b5'	System	17 Aug 2020 17:31:07
User entered 'None (1)'	System	17 Aug 2020 17:31:07

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-17T13:31:07', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'c051947a-3b23-4a91-a36d-f55b6d3ac3b5'	System	17 Aug 2020 17:31:07
User entered '17 Aug 2020 13:31'	System	17 Aug 2020 17:31:07

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 5'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-18T13:19:19', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '7f2de0bc-264f-463b-97f7-ed37d9aa2fc6'	System	18 Aug 2020 17:20:14
User entered 'None (1)'	System	18 Aug 2020 17:20:14



US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-18T13:19:36', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '7f2de0bc-264f-463b-97f7-ed37d9aa2fc6'	System	18 Aug 2020 17:20:14
User entered 'No (N)'	System	18 Aug 2020 17:20:14

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-18T13:19:42', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '7f2de0bc-264f-463b-97f7-ed37d9aa2fc6'	System	18 Aug 2020 17:20:14
User entered 'No (N)'	System	18 Aug 2020 17:20:14

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-18T13:19:55', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '7f2de0bc-264f-463b-97f7-ed37d9aa2fc6'	System	18 Aug 2020 17:20:14
User entered 'None (1)'	System	18 Aug 2020 17:20:14

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-18T13:20:11', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '7f2de0bc-264f-463b-97f7-ed37d9aa2fc6'	System	18 Aug 2020 17:20:14
User entered '18 Aug 2020 13:20'	System	18 Aug 2020 17:20:14

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 6'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-19T18:58:49', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '63ef7b72-9329-4e1a-a990-826bf7b57874'	System	19 Aug 2020 22:59:31
User entered 'None (1)'	System	19 Aug 2020 22:59:31



US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-19T18:58:58', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '63ef7b72-9329-4e1a-a990-826bf7b57874'	System	19 Aug 2020 22:59:31
User entered 'No (N)'	System	19 Aug 2020 22:59:31

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-19T18:59:06', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '63ef7b72-9329-4e1a-a990-826bf7b57874'	System	19 Aug 2020 22:59:31
User entered 'No (N)'	System	19 Aug 2020 22:59:31

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-19T18:59:13', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '63ef7b72-9329-4e1a-a990-826bf7b57874'	System	19 Aug 2020 22:59:31
User entered 'None (1)'	System	19 Aug 2020 22:59:31

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-19T18:59:33', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '63ef7b72-9329-4e1a-a990-826bf7b57874'	System	19 Aug 2020 22:59:31
User entered '19 Aug 2020 18:59'	System	19 Aug 2020 22:59:31

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 7'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-20T12:47:55', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '15cbc569-5f71-484a-b953-a2858ea362ec'	System	20 Aug 2020 16:48:27
User entered 'None (1)'	System	20 Aug 2020 16:48:27



US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-20T12:47:59', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '15cbc569-5f71-484a-b953-a2858ea362ec'	System	20 Aug 2020 16:48:27
User entered 'No (N)'	System	20 Aug 2020 16:48:27

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-20T12:48:06', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '15cbc569-5f71-484a-b953-a2858ea362ec'	System	20 Aug 2020 16:48:27
User entered 'No (N)'	System	20 Aug 2020 16:48:27

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-20T12:48:12', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '15cbc569-5f71-484a-b953-a2858ea362ec'	System	20 Aug 2020 16:48:27
User entered 'None (1)'	System	20 Aug 2020 16:48:27

US3052220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-20T12:48:29', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '15cbc569-5f71-484a-b953-a2858ea362ec'	System	20 Aug 2020 16:48:27
User entered '20 Aug 2020 12:48'	System	20 Aug 2020 16:48:27

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T13:12:08', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '2b75e442-fd79-4250-b24e-3faffcd42b01'	System	14 Aug 2020 17:12:58
User entered 'None (0)'	System	14 Aug 2020 17:12:58



US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T13:12:14', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '2b75e442-fd79-4250-b24e-3faffcd42b01'	System	14 Aug 2020 17:12:58
User entered 'None (0)'	System	14 Aug 2020 17:12:58

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T13:12:19', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '2b75e442-fd79-4250-b24e-3faffcd42b01'	System	14 Aug 2020 17:12:58
User entered 'None (0)'	System	14 Aug 2020 17:12:58

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T13:12:23', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '2b75e442-fd79-4250-b24e-3faffcd42b01'	System	14 Aug 2020 17:12:58
User entered 'None (0)'	System	14 Aug 2020 17:12:58

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T13:12:28', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '2b75e442-fd79-4250-b24e-3faffcd42b01'	System	14 Aug 2020 17:12:58
User entered 'None (0)'	System	14 Aug 2020 17:12:58

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T13:12:37', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '2b75e442-fd79-4250-b24e-3faffcd42b01'	System	14 Aug 2020 17:12:58
User entered 'None (0)'	System	14 Aug 2020 17:12:58

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

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)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T13:12:44', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '2b75e442-fd79-4250-b24e-3faffcd42b01'	System	14 Aug 2020 17:12:58
User entered 'No (N)'	System	14 Aug 2020 17:12:58

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T13:12:51', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '2b75e442-fd79-4250-b24e-3faffcd42b01'	System	14 Aug 2020 17:12:58
User entered '14 Aug 2020 13:12'	System	14 Aug 2020 17:12:58

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '14 Aug 2020 12:49'	System	14 Aug 2020 16:37:22



**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '14 Aug 2020 15:19'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T17:35:29', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '582c9af8-8393-4be6-a9c0-ce6e614d3afe'	System	14 Aug 2020 21:36:25
User entered 'None (0)'	System	14 Aug 2020 21:36:25

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T17:35:35', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '582c9af8-8393-4be6-a9c0-ce6e614d3afe'	System	14 Aug 2020 21:36:25
User entered 'None (0)'	System	14 Aug 2020 21:36:25

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T17:35:44', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '582c9af8-8393-4be6-a9c0-ce6e614d3afe'	System	14 Aug 2020 21:36:25
User entered 'None (0)'	System	14 Aug 2020 21:36:25

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T17:35:51', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '582c9af8-8393-4be6-a9c0-ce6e614d3afe'	System	14 Aug 2020 21:36:25
User entered 'None (0)'	System	14 Aug 2020 21:36:25

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T17:35:56', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '582c9af8-8393-4be6-a9c0-ce6e614d3afe'	System	14 Aug 2020 21:36:25
User entered 'None (0)'	System	14 Aug 2020 21:36:25

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T17:36:02', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '582c9af8-8393-4be6-a9c0-ce6e614d3afe'	System	14 Aug 2020 21:36:25
User entered 'None (0)'	System	14 Aug 2020 21:36:25



US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

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)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T17:36:09', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '582c9af8-8393-4be6-a9c0-ce6e614d3afe'	System	14 Aug 2020 21:36:25
User entered 'No (N)'	System	14 Aug 2020 21:36:25

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-14T17:36:22', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '582c9af8-8393-4be6-a9c0-ce6e614d3afe'	System	14 Aug 2020 21:36:25
User entered '14 Aug 2020 17:36'	System	14 Aug 2020 21:36:25

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '14 Aug 2020 16:14'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 2'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-15T13:32:57', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '14f2fb71-c370-4ad1-9a04-e68faa9eced8'	System	15 Aug 2020 17:33:50
User entered 'None (0)'	System	15 Aug 2020 17:33:50

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-15T13:33:02', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '14f2fb71-c370-4ad1-9a04-e68faa9eced8'	System	15 Aug 2020 17:33:50
User entered 'None (0)'	System	15 Aug 2020 17:33:50

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-15T13:33:06', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '14f2fb71-c370-4ad1-9a04-e68faa9eced8'	System	15 Aug 2020 17:33:50
User entered 'None (0)'	System	15 Aug 2020 17:33:50



US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-15T13:33:11', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '14f2fb71-c370-4ad1-9a04-e68faa9eced8'	System	15 Aug 2020 17:33:50
User entered 'None (0)'	System	15 Aug 2020 17:33:50

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-15T13:33:18', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '14f2fb71-c370-4ad1-9a04-e68faa9eced8'	System	15 Aug 2020 17:33:50
User entered 'None (0)'	System	15 Aug 2020 17:33:50

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-15T13:33:22', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '14f2fb71-c370-4ad1-9a04-e68faa9eced8'	System	15 Aug 2020 17:33:50
User entered 'None (0)'	System	15 Aug 2020 17:33:50

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

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)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-15T13:33:29', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '14f2fb71-c370-4ad1-9a04-e68faa9eced8'	System	15 Aug 2020 17:33:50
User entered 'No (N)'	System	15 Aug 2020 17:33:50

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-15T13:33:48', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '14f2fb71-c370-4ad1-9a04-e68faa9eced8'	System	15 Aug 2020 17:33:50
User entered '15 Aug 2020 13:33'	System	15 Aug 2020 17:33:50

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 3'	System	14 Aug 2020 16:37:22



US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-16T14:30:22', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '0b8c4919-0a46-4f7d-a3f1-09329d27a064'	System	16 Aug 2020 18:31:20
User entered 'None (0)'	System	16 Aug 2020 18:31:20

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-16T14:30:28', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '0b8c4919-0a46-4f7d-a3f1-09329d27a064'	System	16 Aug 2020 18:31:20
User entered 'None (0)'	System	16 Aug 2020 18:31:20

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-16T14:30:35', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '0b8c4919-0a46-4f7d-a3f1-09329d27a064'	System	16 Aug 2020 18:31:20
User entered 'None (0)'	System	16 Aug 2020 18:31:20

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-16T14:30:41', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '0b8c4919-0a46-4f7d-a3f1-09329d27a064'	System	16 Aug 2020 18:31:20
User entered 'None (0)'	System	16 Aug 2020 18:31:20

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-16T14:30:46', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '0b8c4919-0a46-4f7d-a3f1-09329d27a064'	System	16 Aug 2020 18:31:20
User entered 'None (0)'	System	16 Aug 2020 18:31:20

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-16T14:30:52', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '0b8c4919-0a46-4f7d-a3f1-09329d27a064'	System	16 Aug 2020 18:31:20
User entered 'None (0)'	System	16 Aug 2020 18:31:20

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

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)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-16T14:31:01', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '0b8c4919-0a46-4f7d-a3f1-09329d27a064'	System	16 Aug 2020 18:31:20
User entered 'No (N)'	System	16 Aug 2020 18:31:20

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-16T14:31:19', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '0b8c4919-0a46-4f7d-a3f1-09329d27a064'	System	16 Aug 2020 18:31:20
User entered '16 Aug 2020 14:31'	System	16 Aug 2020 18:31:20



**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 4'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-17T13:31:20', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '4556cc56-2dbf-497e-a1f6-d53fd2916f92'	System	17 Aug 2020 17:32:12
User entered 'None (0)'	System	17 Aug 2020 17:32:12

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-17T13:31:26', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '4556cc56-2dbf-497e-a1f6-d53fd2916f92'	System	17 Aug 2020 17:32:12
User entered 'None (0)'	System	17 Aug 2020 17:32:12

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-17T13:31:33', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '4556cc56-2dbf-497e-a1f6-d53fd2916f92'	System	17 Aug 2020 17:32:12
User entered 'None (0)'	System	17 Aug 2020 17:32:12

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-17T13:31:39', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '4556cc56-2dbf-497e-a1f6-d53fd2916f92'	System	17 Aug 2020 17:32:12
User entered 'None (0)'	System	17 Aug 2020 17:32:12

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-17T13:31:43', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '4556cc56-2dbf-497e-a1f6-d53fd2916f92'	System	17 Aug 2020 17:32:12
User entered 'None (0)'	System	17 Aug 2020 17:32:12



US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-17T13:31:48', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '4556cc56-2dbf-497e-a1f6-d53fd2916f92'	System	17 Aug 2020 17:32:12
User entered 'None (0)'	System	17 Aug 2020 17:32:12

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

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)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-17T13:31:54', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '4556cc56-2dbf-497e-a1f6-d53fd2916f92'	System	17 Aug 2020 17:32:12
User entered 'No (N)'	System	17 Aug 2020 17:32:12

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-17T13:32:12', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '4556cc56-2dbf-497e-a1f6-d53fd2916f92'	System	17 Aug 2020 17:32:12
User entered '17 Aug 2020 13:32'	System	17 Aug 2020 17:32:12

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 5'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-18T13:20:57', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '04790cde-211f-4f60-9c64-57bf17dc66c7'	System	18 Aug 2020 17:21:48
User entered 'None (0)'	System	18 Aug 2020 17:21:48

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-18T13:21:02', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '04790cde-211f-4f60-9c64-57bf17dc66c7'	System	18 Aug 2020 17:21:48
User entered 'None (0)'	System	18 Aug 2020 17:21:48



US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-18T13:21:07', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '04790cde-211f-4f60-9c64-57bf17dc66c7'	System	18 Aug 2020 17:21:48
User entered 'None (0)'	System	18 Aug 2020 17:21:48

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-18T13:21:14', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '04790cde-211f-4f60-9c64-57bf17dc66c7'	System	18 Aug 2020 17:21:48
User entered 'None (0)'	System	18 Aug 2020 17:21:48

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-18T13:21:19', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '04790cde-211f-4f60-9c64-57bf17dc66c7'	System	18 Aug 2020 17:21:48
User entered 'None (0)'	System	18 Aug 2020 17:21:48

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-18T13:21:24', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '04790cde-211f-4f60-9c64-57bf17dc66c7'	System	18 Aug 2020 17:21:48
User entered 'None (0)'	System	18 Aug 2020 17:21:48

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

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)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-18T13:21:31', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '04790cde-211f-4f60-9c64-57bf17dc66c7'	System	18 Aug 2020 17:21:48
User entered 'No (N)'	System	18 Aug 2020 17:21:48

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-18T13:21:46', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '04790cde-211f-4f60-9c64-57bf17dc66c7'	System	18 Aug 2020 17:21:48
User entered '18 Aug 2020 13:21'	System	18 Aug 2020 17:21:48

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 16:37:22



US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 6'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-19T18:59:40', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '044608b1-7565-4596-9dd0-b21baa25f7b2'	System	19 Aug 2020 23:00:56
User entered 'None (0)'	System	19 Aug 2020 23:00:56

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-19T18:59:46', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '044608b1-7565-4596-9dd0-b21baa25f7b2'	System	19 Aug 2020 23:00:56
User entered 'None (0)'	System	19 Aug 2020 23:00:56

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-19T18:59:50', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '044608b1-7565-4596-9dd0-b21baa25f7b2'	System	19 Aug 2020 23:00:56
User entered 'None (0)'	System	19 Aug 2020 23:00:56

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-19T18:59:57', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '044608b1-7565-4596-9dd0-b21baa25f7b2'	System	19 Aug 2020 23:00:56
User entered 'None (0)'	System	19 Aug 2020 23:00:56

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-19T19:00:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '044608b1-7565-4596-9dd0-b21baa25f7b2'	System	19 Aug 2020 23:00:56
User entered 'None (0)'	System	19 Aug 2020 23:00:56

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-19T19:00:04', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '044608b1-7565-4596-9dd0-b21baa25f7b2'	System	19 Aug 2020 23:00:56
User entered 'None (0)'	System	19 Aug 2020 23:00:56

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

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)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-19T19:00:10', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '044608b1-7565-4596-9dd0-b21baa25f7b2'	System	19 Aug 2020 23:00:56
User entered 'No (N)'	System	19 Aug 2020 23:00:56



US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-19T19:00:57', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '044608b1-7565-4596-9dd0-b21baa25f7b2'	System	19 Aug 2020 23:00:56
User entered '19 Aug 2020 19:00'	System	19 Aug 2020 23:00:56

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 7'	System	14 Aug 2020 16:37:22

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-20T12:48:39', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'aec9bc7c-73e2-44c0-852e-fdc219088be9'	System	20 Aug 2020 16:49:55
User entered 'None (0)'	System	20 Aug 2020 16:49:55

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-20T12:49:28', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'aec9bc7c-73e2-44c0-852e-fdc219088be9'	System	20 Aug 2020 16:49:55
User entered 'None (0)'	System	20 Aug 2020 16:49:55

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-20T12:48:49', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'aec9bc7c-73e2-44c0-852e-fdc219088be9'	System	20 Aug 2020 16:49:55
User entered 'None (0)'	System	20 Aug 2020 16:49:55

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-20T12:48:54', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'aec9bc7c-73e2-44c0-852e-fdc219088be9'	System	20 Aug 2020 16:49:55
User entered 'None (0)'	System	20 Aug 2020 16:49:55



US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-20T12:49:03', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'aec9bc7c-73e2-44c0-852e-fdc219088be9'	System	20 Aug 2020 16:49:55
User entered 'None (0)'	System	20 Aug 2020 16:49:55

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-20T12:49:11', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'aec9bc7c-73e2-44c0-852e-fdc219088be9'	System	20 Aug 2020 16:49:55
User entered 'None (0)'	System	20 Aug 2020 16:49:55

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

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)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-20T12:49:18', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'aec9bc7c-73e2-44c0-852e-fdc219088be9'	System	20 Aug 2020 16:49:55
User entered 'No (N)'	System	20 Aug 2020 16:49:55

US3052220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-08-20T12:49:57', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'aec9bc7c-73e2-44c0-852e-fdc219088be9'	System	20 Aug 2020 16:49:55
User entered '20 Aug 2020 12:49'	System	20 Aug 2020 16:49:55

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 16:37:22

**US3052220**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	15 Dec 2020 17:44:26
Query 'Please review source as there is a safety call within the Day 8 window on 24 Aug 2020. Update EDC accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 17:43:01
User entered 'Yes (Y)' reason for change: Data Entry Error		10 Dec 2020 20:47:59
User opened query 'Please review source as there is a safety call within the Day 8 window on 24 Aug 2020. Update EDC accordingly.' (Site from CRA).		19 Nov 2020 16:29:10
User closed query 'Source is unclear. It appears that there are two Day 8 Safety Calls. Please reconcile and updated as needed.' (Site from CRA).		19 Nov 2020 16:27:43
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	30 Oct 2020 12:52:26
Query 'Source is unclear. It appears that there are two Avia McClain-Stocker Day 8 Safety Calls. Please reconcile and updated as needed.' answered with 'reviewed source and updated accordingly' (Site from CRA).	(b) (4)	30 Oct 2020 12:52:16
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	30 Oct 2020 12:52:02
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	30 Oct 2020 12:52:02
User opened query 'Source is unclear. It appears that there are two Day 8 Safety Calls. Please reconcile and updated as needed.' (Site from CRA).	(b) (4), (b) (6)	17 Sep 2020 16:12:47
DataPoint Un-verified.	(b) (4), (b) (6)	17 Sep 2020 16:09:36
DataPoint Verified.		17 Sep 2020 16:09:27
User entered 'Yes (Y)'		31 Aug 2020 14:00:19

US3052220

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 06:06:32
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'date confirmed' (Site from System).	(b) (4), (b) (6)	15 Feb 2021 18:04:58
DataPoint Verified.		15 Dec 2020 17:44:26
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		10 Dec 2020 20:47:59
User entered '26 Aug 2020' reason for change: Data Entry Error		10 Dec 2020 20:47:59
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker	30 Oct 2020 12:52:26
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 16:09:37
DataPoint Verified.		17 Sep 2020 16:09:27
User entered '24 Aug 2020'		31 Aug 2020 14:00:19



US3052220

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 17:44:26
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4)	10 Dec 2020 20:47:59
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker	30 Oct 2020 12:52:26
DataPoint Un-verified.	(b) (4), (b) (6)	17 Sep 2020 16:09:39
DataPoint Verified.	(b) (4)	17 Sep 2020 16:09:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	31 Aug 2020 14:00:19

US3052220

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:44:26
DataPoint Un-verified.		17 Sep 2020 16:09:40
DataPoint Verified.		17 Sep 2020 16:09:27
User entered empty.		31 Aug 2020 14:00:19

US3052220

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:44:31
DataPoint Un-verified.		03 Dec 2020 17:27:52
DataPoint Verified.		19 Nov 2020 16:21:17
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	17 Sep 2020 16:10:19

**US3052220**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'I'	System	17 Sep 2020 16:10:19

**US3052220**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:23:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	04 Nov 2020 20:50:02
User entered 'No (N)'	Avia McClain-Stocker (b) (4)	30 Oct 2020 12:52:36

US3052220

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:23:21
User closed query 'Per source, there is a safety call on 01Sep 2020(1 day out of window). This is the next call following the 24 Aug 2020 which is within the Day 8 timeline. Please review source and clarify which call was which date. ' (Site from CRA).		21 Feb 2021 05:07:06
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).		16 Feb 2021 07:19:54
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'confirmed date' (Site from System).		15 Feb 2021 18:10:49
Query 'Per source, there is a safety call on 01Sep 2020(1 day out of window). This is the next call following the 24 Aug 2020 which is within the Day 8 timeline. Please review source and clarify which call was which date. ' answered with 'reviewed and updated' (Site from CRA).		15 Feb 2021 18:10:36
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Feb 2021 18:10:19
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 18:10:19
User opened query 'Per source, there is a safety call on 01Sep 2020(1 day out of window). This is the next call following the 24 Aug 2020 which is within the Day 8 timeline. Please review source and clarify which call was which date. ' (Site from CRA).		19 Nov 2020 16:32:31

US3052220

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 07:49:06
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	Avia McClain-Stocker	04 Nov 2020 20:50:14
answered with 'CALL DATE CONFIRMED PER SOURCE DOCUMENT' (Site from System).	(b) (4)	
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	04 Nov 2020 20:50:02
User entered '24 Aug 2020' reason for change: Data Entry Error	Avia McClain-Stocker	04 Nov 2020 20:50:02
User entered empty.	(b) (4)	
	Avia McClain-Stocker	30 Oct 2020 12:52:36
	(b) (4)	

US3052220

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:23:21
User entered 'Contact Made (CONTACT MADE)'	Avia McClain-Stocker	04 Nov 2020 20:50:02
reason for change: Data Entry Error	(b) (4)	
User entered empty.	Avia McClain-Stocker	30 Oct 2020 12:52:36
	(b) (4)	



US3052220

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:23:21
User entered empty.	Avia McClain-Stocker (b) (4)	30 Oct 2020 12:52:36

US3052220

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:24:13
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	17 Sep 2020 16:10:26

**US3052220**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'I'	System	17 Sep 2020 16:10:26

US3052220

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:26:00
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Feb 2021 18:13:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Feb 2021 18:13:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 18:13:33
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Feb 2021 18:13:29
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	15 Feb 2021 18:13:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 18:13:29
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	15 Feb 2021 18:13:24
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	30 Oct 2020 12:53:30

US3052220

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:00
User closed query 'There is no source record for this call. Please review subject source and reconcile as appropriate' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 15:25:59
Query 'There is no source record for this call. Please review subject source and reconcile as appropriate' answered with 'reviewed and updated' (Site from CRA).	(b) (4), (b) (6)	15 Feb 2021 18:13:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 18:13:24
User opened query 'There is no source record for this call. Please review subject source and reconcile as appropriate' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 17:51:11
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 19:32:07
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'confirmed date of call per source' (Site from System).	Avia McClain-Stocker (b) (4)	30 Oct 2020 12:54:25
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	30 Oct 2020 12:53:30
User entered '25 Aug 2020'	Avia McClain-Stocker (b) (4)	30 Oct 2020 12:53:30

US3052220

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:26:00
User entered empty; reason for change Data Entry Error		15 Feb 2021 18:13:24
User entered 'Contact Made (CONTACT MADE)'	Avia McClain-Stocker (b) (4)	30 Oct 2020 12:53:30

US3052220

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:26:00
User entered empty.	Avia McClain-Stocker (b) (4)	30 Oct 2020 12:53:30

US3052220

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:52:45
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	17 Sep 2020 16:10:33



**US3052220**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'I'	System	17 Sep 2020 16:10:33

US3052220

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	03 Dec 2020 17:59:15
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 17SEP2020 is reported under Visit 2 Day 29visit 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)	18 Nov 2020 10:50:07
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 17SEP2020 is reported under Visit 2 Day 29visit 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 'REVIEW AND UPDATE' (Site from DM).	Stacey Saldua (b) (4)	12 Nov 2020 21:30:28
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 17SEP2020 is reported under Visit 2 Day 29visit 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)	21 Oct 2020 11:30:12
Un-reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 11:30:06
Reviewed for Data Management.	(b) (4), (b) (6)	21 Oct 2020 11:30:02
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	17 Sep 2020 16:10:47
	(b) (4)	

US3052220

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	03 Dec 2020 17:59:15
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 17-Sep-2020 is reported under Visit 2 Day 29 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:48:54
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 17-Sep-2020 is reported under Visit 2 Day 29 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.'	Stacey Saldua (b) (4)	12 Nov 2020 21:30:40
answered with 'review and update' (Site from DM).	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 17-Sep-2020 is reported under Visit 2 Day 29 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:54:47
User entered '17 Sep 2020'	Stacey Saldua (b) (4)	17 Sep 2020 16:10:47
	(b) (4)	

US3052220

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:29

[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 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:15
User entered 'Clinic (Clinic)'	Stacey Saldua (b) (4) (b) (4)	17 Sep 2020 16:10:47

**US3052220**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'VISIT2'	System	17 Sep 2020 16:10:47

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User accepted default value 'Pre-Dose (PREDOSE)'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:36
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:36
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Nov 2020 16:04:54
User entered '17 Sep 2020' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:54
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Nov 2020 16:04:26
User entered '17 Oct 2020'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26



US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:36
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	02 Nov 2020 16:04:54
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	02 Nov 2020 16:04:26
User entered '10:52'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26

**US3052220**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered '17 Sep 2020 10:52'	System	02 Nov 2020 16:04:54
User entered '17 Oct 2020 10:52'	System	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:36
User entered '98.7' F	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 17:59:36
User entered 'Oral (Oral)'	Stacey Saldua (b) (4)	02 Nov 2020 16:04:26
	(b) (4)	

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:36
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:36
User entered '76'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'bpm'	System	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:36
User entered missing code ND - Not Done.	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26



US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'breaths/min'	System	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:36
User entered '126'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'mmHg'	System	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:36
User entered '78'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'mmHg'	System	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User accepted default value 'Post-Dose (POSTDOSE)'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:36
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:36
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Nov 2020 16:04:54
User entered '17 Sep 2020' reason for change: Data Entry Error	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:54
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Nov 2020 16:04:26
User entered '17 Oct 2020'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:36
User entered '12:34'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26

**US3052220**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered '17 Sep 2020 12:34'	System	02 Nov 2020 16:04:54
User entered '17 Oct 2020 12:34'	System	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:36
User entered '98.5' F	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:36
User entered 'Oral (Oral)'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:36
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:36
User entered '71'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'bpm'	System	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:36
User entered '14'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26



US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'breaths/min'	System	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:36
User entered '127'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'mmHg'	System	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:59:36
User entered '78'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'mmHg'	System	02 Nov 2020 16:04:26

US3052220

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:00:39
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	17 Sep 2020 16:10:55

US3052220

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:00:39
User entered '17 Sep 2020'	Stacey Saldua (b) (4) (b) (4)	17 Sep 2020 16:10:55

US3052220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:01:00
User closed query 'Per CDM: Please complete the following forms: VITAL SIGNS DOSING; NASOPHARYNGEAL, and IMMUNOGENICITY.' (Site from DM).		04 Nov 2020 05:56:10
Query 'Per CDM: Please complete the following forms: VITAL SIGNS DOSING; NASOPHARYNGEAL, and IMMUNOGENICITY.' answered with 'review and update' (Site from DM).	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:07:45
User opened query 'Per CDM: Please complete the following forms: VITAL SIGNS DOSING; NASOPHARYNGEAL, and IMMUNOGENICITY.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 11:28:37
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	17 Sep 2020 16:11:21



US3052220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:01:00
User entered empty.	Stacey Saldua (b) (4) (b) (4)	17 Sep 2020 16:11:21

US3052220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

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 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:01:00
User entered empty.	Stacey Saldua (b) (4) (b) (4)	17 Sep 2020 16:11:21

US3052220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 16:11:21

US3052220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	03 Dec 2020 18:01:00
User closed query 'Per GCL Lab Recon: it appears GCL has a nasopharyngeal sample with date of 17SEP2020 however the form is not completed in EDC.. Please complete' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 11:54:05
Query 'Per GCL Lab Recon: it appears GCL has a nasopharyngeal sample with date of 17SEP2020 however the form is not completed in EDC.. Please complete' answered with 'review and update' (Site from DM).	Stacey Saldua (b) (4)	02 Nov 2020 16:08:12
User opened query 'Per GCL Lab Recon: it appears GCL has a nasopharyngeal sample with date of 17SEP2020 however the form is not completed in EDC.. Please complete' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 12:59:02
User entered '17 Sep 2020'	Stacey Saldua (b) (4)	17 Sep 2020 16:11:21

US3052220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:01:00
User entered '11:54'	Stacey Saldua (b) (4) (b) (4)	17 Sep 2020 16:11:21

US3052220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered '17 Sep 2020 11:54'	System	17 Sep 2020 16:11:21

US3052220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:01:00
User entered 'Left Arm (LEFT ARM)'	Stacey Saldua (b) (4) (b) (4)	17 Sep 2020 16:11:21

US3052220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
DataPoint Verified.		03 Dec 2020 18:01:00
User entered 'ONCE'	System	17 Sep 2020 16:11:21



US3052220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 16:11:21

US3052220

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:01:09
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:06:46

US3052220

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:01:09
User entered '17 Sep 2020'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:06:46

US3052220

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:01:09
User entered '10:25'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:06:46

**US3052220**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered '17 Sep 2020 10:25'	System	02 Nov 2020 16:06:46

US3052220

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:56:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:01:16
User entered '17 Sep 2020'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:07:19

**US3052220**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:07:19

US3052220

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:56:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:01:16
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:07:19



**US3052220**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:01:16
User entered '10:27'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:07:19

**US3052220**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered '17 Sep 2020 10:27'	System	02 Nov 2020 16:07:19

**US3052220**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:07:19

US3052220

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:01:16
User entered 'No (N)' reason for change: Data Entry Error	Stacey Saldua (b) (4)	02 Nov 2020 16:07:26
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:07:19

US3052220

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:56:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:01:16
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	02 Nov 2020 16:07:26
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	02 Nov 2020 16:07:26
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	02 Nov 2020 16:07:19
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:07:19

**US3052220**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered empty.	System	02 Nov 2020 16:07:19

US3052220

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:01:21
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:17:22

**US3052220**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'I'	System	21 Oct 2020 20:17:22



US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T12:34:55', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '7a377db7-f84b-497e-a2e8-c59057ec3bdd'	System	17 Sep 2020 16:36:51
User entered 'Yes (Y)'	System	17 Sep 2020 16:36:51

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T12:35:02', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '7a377db7-f84b-497e-a2e8-c59057ec3bdd'	System	17 Sep 2020 16:36:51
User entered '98.5'	System	17 Sep 2020 16:36:51

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T12:35:07', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '7a377db7-f84b-497e-a2e8-c59057ec3bdd'	System	17 Sep 2020 16:36:51
User entered 'No (N)'	System	17 Sep 2020 16:36:51

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T12:36:45', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '7a377db7-f84b-497e-a2e8-c59057ec3bdd'	System	17 Sep 2020 16:36:51
User entered '17 Sep 2020 12:36'	System	17 Sep 2020 16:36:51

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '17 Sep 2020 12:14'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '17 Sep 2020 14:44'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 16:11:21



US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T21:07:42', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '86ad687e-f910-4fa6-a71f-9f6285dd7930'	System	18 Sep 2020 01:08:23
User entered 'Yes (Y)'	System	18 Sep 2020 01:08:23

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T21:07:55', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '86ad687e-f910-4fa6-a71f-9f6285dd7930'	System	18 Sep 2020 01:08:23
User entered '97.5'	System	18 Sep 2020 01:08:23

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T21:08:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '86ad687e-f910-4fa6-a71f-9f6285dd7930'	System	18 Sep 2020 01:08:23
User entered 'No (N)'	System	18 Sep 2020 01:08:23

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T21:08:21', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '86ad687e-f910-4fa6-a71f-9f6285dd7930'	System	18 Sep 2020 01:08:23
User entered '17 Sep 2020 21:08'	System	18 Sep 2020 01:08:23

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '17 Sep 2020 15:39'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 2'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-18T12:46:25', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3006d14a-8563-442c-a213-e29e33e16a81'	System	18 Sep 2020 16:50:34
User entered 'Yes (Y)'	System	18 Sep 2020 16:50:34



US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-18T12:50:18', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3006d14a-8563-442c-a213-e29e33e16a81'	System	18 Sep 2020 16:50:34
User entered '97.8'	System	18 Sep 2020 16:50:34

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-18T12:50:22', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3006d14a-8563-442c-a213-e29e33e16a81'	System	18 Sep 2020 16:50:34
User entered 'No (N)'	System	18 Sep 2020 16:50:34

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-18T12:50:32', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3006d14a-8563-442c-a213-e29e33e16a81'	System	18 Sep 2020 16:50:34
User entered '18 Sep 2020 12:50'	System	18 Sep 2020 16:50:34

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 3'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-19T15:38:22', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '78a4cf83-8dae-4c5f-a465-b4a09b8ad889'	System	19 Sep 2020 19:42:51
User entered 'Yes (Y)'	System	19 Sep 2020 19:42:51

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-19T15:42:38', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '78a4cf83-8dae-4c5f-a465-b4a09b8ad889'	System	19 Sep 2020 19:42:51
User entered '97.9'	System	19 Sep 2020 19:42:51



US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-19T15:42:43', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '78a4cf83-8dae-4c5f-a465-b4a09b8ad889'	System	19 Sep 2020 19:42:51
User entered 'No (N)'	System	19 Sep 2020 19:42:51

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-19T15:42:51', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '78a4cf83-8dae-4c5f-a465-b4a09b8ad889'	System	19 Sep 2020 19:42:51
User entered '19 Sep 2020 15:42'	System	19 Sep 2020 19:42:51

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 4'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-20T14:13:16', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '20e83cc8-c5d0-47f5-aa70-ceb17c8a200e'	System	20 Sep 2020 18:13:57
User entered 'Yes (Y)'	System	20 Sep 2020 18:13:57

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-20T14:13:40', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '20e83cc8-c5d0-47f5-aa70-ceb17c8a200e' User entered '97.5'	System	20 Sep 2020 18:13:57
	System	20 Sep 2020 18:13:57

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-20T14:13:44', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '20e83cc8-c5d0-47f5-aa70-ceb17c8a200e'	System	20 Sep 2020 18:13:57
User entered 'No (N)'	System	20 Sep 2020 18:13:57



US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-20T14:13:56', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '20e83cc8-c5d0-47f5-aa70-ceb17c8a200e'	System	20 Sep 2020 18:13:57
User entered '20 Sep 2020 14:13'	System	20 Sep 2020 18:13:57

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 5'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-21T14:41:57', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '7fbfb09a-72cc-4d7e-82c9-f0d2d95db216'	System	21 Sep 2020 18:42:19
User entered 'Yes (Y)'	System	21 Sep 2020 18:42:19

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-21T14:42:05', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '7fbfb09a-72cc-4d7e-82c9-f0d2d95db216'	System	21 Sep 2020 18:42:19
User entered '97.4'	System	21 Sep 2020 18:42:19

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-21T14:42:09', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '7fbfb09a-72cc-4d7e-82c9-f0d2d95db216'	System	21 Sep 2020 18:42:19
User entered 'No (N)'	System	21 Sep 2020 18:42:19

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-21T14:42:19', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '7fbfb09a-72cc-4d7e-82c9-f0d2d95db216'	System	21 Sep 2020 18:42:19
User entered '21 Sep 2020 14:42'	System	21 Sep 2020 18:42:19



US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 6'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-22T16:31:36', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '43e3c4f5-fc2a-461c-beaf-d725baaa4dd2'	System	22 Sep 2020 20:32:05
User entered 'Yes (Y)'	System	22 Sep 2020 20:32:05

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-22T16:31:45', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '43e3c4f5-fc2a-461c-beaf-d725baaa4dd2'	System	22 Sep 2020 20:32:05
User entered '98.0'	System	22 Sep 2020 20:32:05

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-22T16:31:49', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '43e3c4f5-fc2a-461c-beaf-d725baaa4dd2'	System	22 Sep 2020 20:32:05
User entered 'No (N)'	System	22 Sep 2020 20:32:05

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-22T16:32:03', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '43e3c4f5-fc2a-461c-beaf-d725baaa4dd2'	System	22 Sep 2020 20:32:05
User entered '22 Sep 2020 16:32'	System	22 Sep 2020 20:32:05

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 16:11:21



US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 7'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-23T13:43:53', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '30bd563f-799d-4943-9a28-645715744f95'	System	23 Sep 2020 17:47:44
User entered 'Yes (Y)'	System	23 Sep 2020 17:47:44

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-23T13:47:24', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '30bd563f-799d-4943-9a28-645715744f95'	System	23 Sep 2020 17:47:44
User entered '98.3'	System	23 Sep 2020 17:47:44

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-23T13:47:29', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '30bd563f-799d-4943-9a28-645715744f95'	System	23 Sep 2020 17:47:44
User entered 'No (N)'	System	23 Sep 2020 17:47:44

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-23T13:47:43', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '30bd563f-799d-4943-9a28-645715744f95'	System	23 Sep 2020 17:47:44
User entered '23 Sep 2020 13:47'	System	23 Sep 2020 17:47:44

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 16:11:21



US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T12:36:57', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'cc475e2c-2596-4b21-a3b4-33605e9c65f0'	System	17 Sep 2020 16:37:30
User entered 'None (1)'	System	17 Sep 2020 16:37:30

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T12:37:02', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'cc475e2c-2596-4b21-a3b4-33605e9c65f0'	System	17 Sep 2020 16:37:30
User entered 'No (N)'	System	17 Sep 2020 16:37:30

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T12:37:12', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'cc475e2c-2596-4b21-a3b4-33605e9c65f0'	System	17 Sep 2020 16:37:30
User entered 'No (N)'	System	17 Sep 2020 16:37:30

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T12:37:17', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'cc475e2c-2596-4b21-a3b4-33605e9c65f0'	System	17 Sep 2020 16:37:30
User entered 'None (1)'	System	17 Sep 2020 16:37:30

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T12:37:27', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'cc475e2c-2596-4b21-a3b4-33605e9c65f0'	System	17 Sep 2020 16:37:30
User entered '17 Sep 2020 12:37'	System	17 Sep 2020 16:37:30

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '17 Sep 2020 12:14'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '17 Sep 2020 14:44'	System	17 Sep 2020 16:11:21



US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T21:08:31', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '8e5dc7bd-8bd0-4c4c-849e-ee2ac5ba79c9'	System	18 Sep 2020 01:09:08
User entered 'None (1)'	System	18 Sep 2020 01:09:08

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T21:08:35', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '8e5dc7bd-8bd0-4c4c-849e-ee2ac5ba79c9'	System	18 Sep 2020 01:09:08
User entered 'No (N)'	System	18 Sep 2020 01:09:08

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T21:08:39', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '8e5dc7bd-8bd0-4c4c-849e-ee2ac5ba79c9'	System	18 Sep 2020 01:09:08
User entered 'No (N)'	System	18 Sep 2020 01:09:08

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T21:08:47', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '8e5dc7bd-8bd0-4c4c-849e-ee2ac5ba79c9'	System	18 Sep 2020 01:09:08
User entered 'None (1)'	System	18 Sep 2020 01:09:08

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T21:09:04', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '8e5dc7bd-8bd0-4c4c-849e-ee2ac5ba79c9'	System	18 Sep 2020 01:09:08
User entered '17 Sep 2020 21:09'	System	18 Sep 2020 01:09:08

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '17 Sep 2020 15:39'	System	17 Sep 2020 16:11:21

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 16:11:21



US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 2'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-18T12:50:54', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '99687a52-61b3-41a9-8369-69e8a39d68e4'	System	18 Sep 2020 16:51:28
User entered 'None (1)'	System	18 Sep 2020 16:51:28

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-18T12:51:01', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '99687a52-61b3-41a9-8369-69e8a39d68e4'	System	18 Sep 2020 16:51:28
User entered 'No (N)'	System	18 Sep 2020 16:51:28

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-18T12:51:05', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '99687a52-61b3-41a9-8369-69e8a39d68e4'	System	18 Sep 2020 16:51:28
User entered 'No (N)'	System	18 Sep 2020 16:51:28

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-18T12:51:13', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '99687a52-61b3-41a9-8369-69e8a39d68e4'	System	18 Sep 2020 16:51:28
User entered 'None (1)'	System	18 Sep 2020 16:51:28

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-18T12:51:25', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '99687a52-61b3-41a9-8369-69e8a39d68e4'	System	18 Sep 2020 16:51:28
User entered '18 Sep 2020 12:51'	System	18 Sep 2020 16:51:28

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 16:11:21

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 16:11:21



US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 3'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-19T15:43:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '877bc598-1f21-4b5b-93a5-97ecb86efa39'	System	19 Sep 2020 19:43:40
User entered 'None (1)'	System	19 Sep 2020 19:43:40

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-19T15:43:03', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '877bc598-1f21-4b5b-93a5-97ecb86efa39'	System	19 Sep 2020 19:43:40
User entered 'No (N)'	System	19 Sep 2020 19:43:40

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-19T15:43:07', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '877bc598-1f21-4b5b-93a5-97ecb86efa39'	System	19 Sep 2020 19:43:40
User entered 'No (N)'	System	19 Sep 2020 19:43:40

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-19T15:43:13', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '877bc598-1f21-4b5b-93a5-97ecb86efa39'	System	19 Sep 2020 19:43:40
User entered 'None (1)'	System	19 Sep 2020 19:43:40

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-19T15:43:39', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '877bc598-1f21-4b5b-93a5-97ecb86efa39'	System	19 Sep 2020 19:43:40
User entered '19 Sep 2020 15:43'	System	19 Sep 2020 19:43:40

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 16:11:21



US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 4'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-20T14:14:43', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'a1c07d2b-46c2-4e5c-ac9b-0a4377927b44'	System	20 Sep 2020 18:15:23
User entered 'None (1)'	System	20 Sep 2020 18:15:23

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-20T14:14:46', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'a1c07d2b-46c2-4e5c-ac9b-0a4377927b44'	System	20 Sep 2020 18:15:23
User entered 'No (N)'	System	20 Sep 2020 18:15:23

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-20T14:14:54', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'a1c07d2b-46c2-4e5c-ac9b-0a4377927b44'	System	20 Sep 2020 18:15:23
User entered 'No (N)'	System	20 Sep 2020 18:15:23

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-20T14:15:03', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'a1c07d2b-46c2-4e5c-ac9b-0a4377927b44'	System	20 Sep 2020 18:15:23
User entered 'None (1)'	System	20 Sep 2020 18:15:23

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-20T14:15:23', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'a1c07d2b-46c2-4e5c-ac9b-0a4377927b44'	System	20 Sep 2020 18:15:23
User entered '20 Sep 2020 14:15'	System	20 Sep 2020 18:15:23

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 16:11:21



US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 5'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-21T14:42:41', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'a905cbf4-0c64-4d33-a2a6-53809d352869'	System	21 Sep 2020 18:43:11
User entered 'Does not interfere with activity (2)'	System	21 Sep 2020 18:43:11

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-21T14:42:45', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'a905cbf4-0c64-4d33-a2a6-53809d352869'	System	21 Sep 2020 18:43:11
User entered 'No (N)'	System	21 Sep 2020 18:43:11

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-21T14:42:49', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'a905cbf4-0c64-4d33-a2a6-53809d352869'	System	21 Sep 2020 18:43:11
User entered 'No (N)'	System	21 Sep 2020 18:43:11

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-21T14:43:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'a905cbf4-0c64-4d33-a2a6-53809d352869'	System	21 Sep 2020 18:43:11
User entered 'None (1)'	System	21 Sep 2020 18:43:11

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-21T14:43:09', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'a905cbf4-0c64-4d33-a2a6-53809d352869'	System	21 Sep 2020 18:43:11
User entered '21 Sep 2020 14:43'	System	21 Sep 2020 18:43:11

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 16:11:21

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 16:11:21



US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 6'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-22T16:32:16', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '12608c90-0f24-460d-94df-9555a47741f8'	System	22 Sep 2020 20:33:17
User entered 'None (1)'	System	22 Sep 2020 20:33:17

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-22T16:32:20', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '12608c90-0f24-460d-94df-9555a47741f8'	System	22 Sep 2020 20:33:17
User entered 'No (N)'	System	22 Sep 2020 20:33:17

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-22T16:32:24', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '12608c90-0f24-460d-94df-9555a47741f8'	System	22 Sep 2020 20:33:17
User entered 'No (N)'	System	22 Sep 2020 20:33:17

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-22T16:32:34', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '12608c90-0f24-460d-94df-9555a47741f8'	System	22 Sep 2020 20:33:17
User entered 'None (1)'	System	22 Sep 2020 20:33:17

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-22T16:32:55', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '12608c90-0f24-460d-94df-9555a47741f8'	System	22 Sep 2020 20:33:17
User entered '22 Sep 2020 16:32'	System	22 Sep 2020 20:33:17

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 16:11:21

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 16:11:21



US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 7'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-23T13:49:13', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '14cded65-1d86-41f4-aeb4-1a4c48589d5f'	System	23 Sep 2020 17:49:55
User entered 'None (1)'	System	23 Sep 2020 17:49:55

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-23T13:49:22', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '14cded65-1d86-41f4-aeb4-1a4c48589d5f'	System	23 Sep 2020 17:49:55
User entered 'No (N)'	System	23 Sep 2020 17:49:55

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-23T13:49:30', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '14cded65-1d86-41f4-aeb4-1a4c48589d5f'	System	23 Sep 2020 17:49:55
User entered 'No (N)'	System	23 Sep 2020 17:49:55

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-23T13:49:43', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '14cded65-1d86-41f4-aeb4-1a4c48589d5f'	System	23 Sep 2020 17:49:55
User entered 'None (1)'	System	23 Sep 2020 17:49:55

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-23T13:49:55', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '14cded65-1d86-41f4-aeb4-1a4c48589d5f'	System	23 Sep 2020 17:49:55
User entered '23 Sep 2020 13:49'	System	23 Sep 2020 17:49:55

US3052220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 16:11:21

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 16:11:21



US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T12:37:34', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '75ef8536-1826-4096-9560-f33066f20bbf'	System	17 Sep 2020 16:38:10
User entered 'None (0)'	System	17 Sep 2020 16:38:10

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T12:37:38', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '75ef8536-1826-4096-9560-f33066f20bbf'	System	17 Sep 2020 16:38:10
User entered 'None (0)'	System	17 Sep 2020 16:38:10

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T12:37:42', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '75ef8536-1826-4096-9560-f33066f20bbf'	System	17 Sep 2020 16:38:10
User entered 'None (0)'	System	17 Sep 2020 16:38:10

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T12:37:45', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '75ef8536-1826-4096-9560-f33066f20bbf'	System	17 Sep 2020 16:38:10
User entered 'None (0)'	System	17 Sep 2020 16:38:10

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T12:37:49', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '75ef8536-1826-4096-9560-f33066f20bbf'	System	17 Sep 2020 16:38:10
User entered 'None (0)'	System	17 Sep 2020 16:38:10

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T12:37:52', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '75ef8536-1826-4096-9560-f33066f20bbf'	System	17 Sep 2020 16:38:10
User entered 'None (0)'	System	17 Sep 2020 16:38:10

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

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)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T12:37:56', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '75ef8536-1826-4096-9560-f33066f20bbf'	System	17 Sep 2020 16:38:10
User entered 'No (N)'	System	17 Sep 2020 16:38:10



US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T12:38:06', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '75ef8536-1826-4096-9560-f33066f20bbf'	System	17 Sep 2020 16:38:10
User entered '17 Sep 2020 12:38'	System	17 Sep 2020 16:38:10

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '17 Sep 2020 12:14'	System	17 Sep 2020 16:11:21

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '17 Sep 2020 14:44'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T21:09:11', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3c528fdb-ad7c-49e9-aecf-b094943692ca'	System	18 Sep 2020 01:10:24
User entered 'None (0)'	System	18 Sep 2020 01:10:24

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T21:09:16', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3c528fdb-ad7c-49e9-aecf-b094943692ca'	System	18 Sep 2020 01:10:24
User entered 'None (0)'	System	18 Sep 2020 01:10:24

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T21:09:22', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3c528fdb-ad7c-49e9-aecf-b094943692ca'	System	18 Sep 2020 01:10:24
User entered 'None (0)'	System	18 Sep 2020 01:10:24

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T21:09:27', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3c528fdb-ad7c-49e9-aecf-b094943692ca'	System	18 Sep 2020 01:10:24
User entered 'None (0)'	System	18 Sep 2020 01:10:24



US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T21:09:31', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3c528fdb-ad7c-49e9-aecf-b094943692ca'	System	18 Sep 2020 01:10:24
User entered 'None (0)'	System	18 Sep 2020 01:10:24

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T21:09:36', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3c528fdb-ad7c-49e9-aecf-b094943692ca'	System	18 Sep 2020 01:10:24
User entered 'None (0)'	System	18 Sep 2020 01:10:24

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

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)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T21:09:47', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3c528fdb-ad7c-49e9-aecf-b094943692ca'	System	18 Sep 2020 01:10:24
User entered 'No (N)'	System	18 Sep 2020 01:10:24

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-17T21:10:04', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3c528fdb-ad7c-49e9-aecf-b094943692ca'	System	18 Sep 2020 01:10:24
User entered '17 Sep 2020 21:10'	System	18 Sep 2020 01:10:24

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '17 Sep 2020 15:39'	System	17 Sep 2020 16:11:21

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 2'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-18T12:51:30', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '51b21666-28fa-46e2-8331-69c9c0f9c412'	System	18 Sep 2020 16:52:20
User entered 'None (0)'	System	18 Sep 2020 16:52:20



US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-18T12:51:36', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '51b21666-28fa-46e2-8331-69c9c0f9c412'	System	18 Sep 2020 16:52:20
User entered 'None (0)'	System	18 Sep 2020 16:52:20

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-18T12:51:41', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '51b21666-28fa-46e2-8331-69c9c0f9c412'	System	18 Sep 2020 16:52:20
User entered 'None (0)'	System	18 Sep 2020 16:52:20

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-18T12:51:45', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '51b21666-28fa-46e2-8331-69c9c0f9c412'	System	18 Sep 2020 16:52:20
User entered 'None (0)'	System	18 Sep 2020 16:52:20

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-18T12:51:48', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '51b21666-28fa-46e2-8331-69c9c0f9c412'	System	18 Sep 2020 16:52:20
User entered 'None (0)'	System	18 Sep 2020 16:52:20

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-18T12:51:51', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '51b21666-28fa-46e2-8331-69c9c0f9c412'	System	18 Sep 2020 16:52:20
User entered 'None (0)'	System	18 Sep 2020 16:52:20

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:29

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)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-18T12:52:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '51b21666-28fa-46e2-8331-69c9c0f9c412'	System	18 Sep 2020 16:52:20
User entered 'No (N)'	System	18 Sep 2020 16:52:20

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-18T12:52:18', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '51b21666-28fa-46e2-8331-69c9c0f9c412'	System	18 Sep 2020 16:52:20
User entered '18 Sep 2020 12:52'	System	18 Sep 2020 16:52:20

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 16:11:21



**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 3'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-19T15:43:51', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3b07a75b-0f5f-4606-96f3-b34bc4273a74'	System	19 Sep 2020 19:45:05
User entered 'None (0)'	System	19 Sep 2020 19:45:05

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-19T15:44:13', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3b07a75b-0f5f-4606-96f3-b34bc4273a74'	System	19 Sep 2020 19:45:05
User entered 'None (0)'	System	19 Sep 2020 19:45:05

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-19T15:44:17', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3b07a75b-0f5f-4606-96f3-b34bc4273a74'	System	19 Sep 2020 19:45:05
User entered 'None (0)'	System	19 Sep 2020 19:45:05

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-19T15:44:22', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3b07a75b-0f5f-4606-96f3-b34bc4273a74'	System	19 Sep 2020 19:45:05
User entered 'None (0)'	System	19 Sep 2020 19:45:05

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-19T15:44:30', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3b07a75b-0f5f-4606-96f3-b34bc4273a74'	System	19 Sep 2020 19:45:05
User entered 'None (0)'	System	19 Sep 2020 19:45:05

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-19T15:44:34', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3b07a75b-0f5f-4606-96f3-b34bc4273a74'	System	19 Sep 2020 19:45:05
User entered 'None (0)'	System	19 Sep 2020 19:45:05



US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

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)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-19T15:44:43', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3b07a75b-0f5f-4606-96f3-b34bc4273a74'	System	19 Sep 2020 19:45:05
User entered 'No (N)'	System	19 Sep 2020 19:45:05

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-19T15:45:02', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3b07a75b-0f5f-4606-96f3-b34bc4273a74'	System	19 Sep 2020 19:45:05
User entered '19 Sep 2020 15:45'	System	19 Sep 2020 19:45:05

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 16:11:21

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 4'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-20T14:15:36', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3164ed2b-4091-40d3-b8b5-128757626c9d'	System	20 Sep 2020 18:16:22
User entered 'None (0)'	System	20 Sep 2020 18:16:22

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-20T14:15:41', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3164ed2b-4091-40d3-b8b5-128757626c9d'	System	20 Sep 2020 18:16:22
User entered 'None (0)'	System	20 Sep 2020 18:16:22

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-20T14:15:46', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3164ed2b-4091-40d3-b8b5-128757626c9d'	System	20 Sep 2020 18:16:22
User entered 'None (0)'	System	20 Sep 2020 18:16:22



US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-20T14:15:50', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3164ed2b-4091-40d3-b8b5-128757626c9d'	System	20 Sep 2020 18:16:22
User entered 'None (0)'	System	20 Sep 2020 18:16:22

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-20T14:15:53', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3164ed2b-4091-40d3-b8b5-128757626c9d'	System	20 Sep 2020 18:16:22
User entered 'None (0)'	System	20 Sep 2020 18:16:22

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-20T14:15:58', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3164ed2b-4091-40d3-b8b5-128757626c9d'	System	20 Sep 2020 18:16:22
User entered 'None (0)'	System	20 Sep 2020 18:16:22

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

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)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-20T14:16:04', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3164ed2b-4091-40d3-b8b5-128757626c9d'	System	20 Sep 2020 18:16:22
User entered 'No (N)'	System	20 Sep 2020 18:16:22

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-20T14:16:23', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '3164ed2b-4091-40d3-b8b5-128757626c9d'	System	20 Sep 2020 18:16:22
User entered '20 Sep 2020 14:16'	System	20 Sep 2020 18:16:22

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 16:11:21

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 5'	System	17 Sep 2020 16:11:21



US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-21T14:43:19', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '84493646-9f5d-475a-9511-4c82077df305'	System	21 Sep 2020 18:44:11
User entered 'None (0)'	System	21 Sep 2020 18:44:11

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-21T14:43:24', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '84493646-9f5d-475a-9511-4c82077df305'	System	21 Sep 2020 18:44:11
User entered 'None (0)'	System	21 Sep 2020 18:44:11

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-21T14:43:28', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '84493646-9f5d-475a-9511-4c82077df305'	System	21 Sep 2020 18:44:11
User entered 'None (0)'	System	21 Sep 2020 18:44:11

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-21T14:43:32', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '84493646-9f5d-475a-9511-4c82077df305'	System	21 Sep 2020 18:44:11
User entered 'None (0)'	System	21 Sep 2020 18:44:11

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-21T14:43:36', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '84493646-9f5d-475a-9511-4c82077df305'	System	21 Sep 2020 18:44:11
User entered 'None (0)'	System	21 Sep 2020 18:44:11

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-21T14:43:40', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '84493646-9f5d-475a-9511-4c82077df305'	System	21 Sep 2020 18:44:11
User entered 'None (0)'	System	21 Sep 2020 18:44:11

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:29

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)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-21T14:43:49', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '84493646-9f5d-475a-9511-4c82077df305'	System	21 Sep 2020 18:44:11
User entered 'No (N)'	System	21 Sep 2020 18:44:11

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-21T14:44:06', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '84493646-9f5d-475a-9511-4c82077df305'	System	21 Sep 2020 18:44:11
User entered '21 Sep 2020 14:44'	System	21 Sep 2020 18:44:11



**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 16:11:21

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 6'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-22T16:33:01', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5d0749c3-746e-4695-aecc-3882a07e5c6c'	System	22 Sep 2020 20:34:19
User entered 'None (0)'	System	22 Sep 2020 20:34:19

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-22T16:33:06', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5d0749c3-746e-4695-aecc-3882a07e5c6c'	System	22 Sep 2020 20:34:19
User entered 'None (0)'	System	22 Sep 2020 20:34:19

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-22T16:33:10', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5d0749c3-746e-4695-aecc-3882a07e5c6c'	System	22 Sep 2020 20:34:19
User entered 'None (0)'	System	22 Sep 2020 20:34:19

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-22T16:33:17', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5d0749c3-746e-4695-aecc-3882a07e5c6c'	System	22 Sep 2020 20:34:19
User entered 'None (0)'	System	22 Sep 2020 20:34:19

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-22T16:33:34', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5d0749c3-746e-4695-aecc-3882a07e5c6c'	System	22 Sep 2020 20:34:19
User entered 'None (0)'	System	22 Sep 2020 20:34:19



US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-22T16:33:41', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5d0749c3-746e-4695-aecc-3882a07e5c6c'	System	22 Sep 2020 20:34:19
User entered 'None (0)'	System	22 Sep 2020 20:34:19

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:29

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)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-22T16:33:47', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5d0749c3-746e-4695-aecc-3882a07e5c6c'	System	22 Sep 2020 20:34:19
User entered 'No (N)'	System	22 Sep 2020 20:34:19

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-22T16:34:17', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5d0749c3-746e-4695-aecc-3882a07e5c6c'	System	22 Sep 2020 20:34:19
User entered '22 Sep 2020 16:34'	System	22 Sep 2020 20:34:19

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 16:11:21

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
Data entry locked.	System	17 Sep 2020 16:11:21
User entered 'Day 7'	System	17 Sep 2020 16:11:21

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-23T13:50:03', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '35ba7d0e-0df7-42e8-9b33-cf7615b64e96'	System	23 Sep 2020 17:50:50
User entered 'None (0)'	System	23 Sep 2020 17:50:50

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-23T13:50:06', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '35ba7d0e-0df7-42e8-9b33-cf7615b64e96'	System	23 Sep 2020 17:50:50
User entered 'None (0)'	System	23 Sep 2020 17:50:50



US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-23T13:50:11', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '35ba7d0e-0df7-42e8-9b33-cf7615b64e96'	System	23 Sep 2020 17:50:50
User entered 'None (0)'	System	23 Sep 2020 17:50:50

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-23T13:50:14', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '35ba7d0e-0df7-42e8-9b33-cf7615b64e96'	System	23 Sep 2020 17:50:50
User entered 'None (0)'	System	23 Sep 2020 17:50:50

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-23T13:50:18', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '35ba7d0e-0df7-42e8-9b33-cf7615b64e96'	System	23 Sep 2020 17:50:50
User entered 'None (0)'	System	23 Sep 2020 17:50:50

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-23T13:50:22', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '35ba7d0e-0df7-42e8-9b33-cf7615b64e96'	System	23 Sep 2020 17:50:50
User entered 'None (0)'	System	23 Sep 2020 17:50:50

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

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)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-23T13:50:27', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '35ba7d0e-0df7-42e8-9b33-cf7615b64e96'	System	23 Sep 2020 17:50:50
User entered 'No (N)'	System	23 Sep 2020 17:50:50

US3052220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-09-23T13:50:49', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '35ba7d0e-0df7-42e8-9b33-cf7615b64e96'	System	23 Sep 2020 17:50:50
User entered '23 Sep 2020 13:50'	System	23 Sep 2020 17:50:50

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 16:11:21

**US3052220**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:25:48
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 16:11:21



US3052220

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	03 Dec 2020 18:32:50
Query 'Per call notes in source, a voicemail was left on phone call attempt. Notes do not specify that contact was eventually made with subject. Please review source and clarify as appropriate. ' canceled (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 18:32:34
User opened query 'Per call notes in source, a voicemail was left on phone call attempt. Notes do not specify that contact was eventually made with subject. Please review source and clarify as appropriate.		03 Dec 2020 18:25:48
' (Site from CRA).		
User entered 'Yes (Y)'	Stacey Saldua (b) (4)	02 Nov 2020 16:09:00
	(b) (4)	

**US3052220**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:32:50
User entered '25 Sep 2020'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:09:00

US3052220

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:32:50
User entered 'Contact Made (CONTACT MADE)'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:09:00

US3052220

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:32:50
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:09:00

US3052220

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:32:55
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:17:30

**US3052220**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'I'	System	21 Oct 2020 20:17:30

US3052220

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:33:18
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:17:44

US3052220

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:33:18
User entered '1 Oct 2020'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:17:44



US3052220

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:33:18
User entered 'Contact Made (CONTACT MADE)'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:17:44

US3052220

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:33:18
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:17:44

US3052220

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:33:24
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:17:36

**US3052220**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'I'	System	21 Oct 2020 20:17:36

**US3052220**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:26:13
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:19:46

**US3052220**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:26:13
User entered '8 Oct 2020'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:19:46

US3052220

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:26:13
User entered 'Contact Made (CONTACT MADE)'	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:19:46

US3052220

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:26:13
User entered empty.	Stacey Saldua (b) (4) (b) (4)	02 Nov 2020 16:19:46



US3052220

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	03 Dec 2020 19:26:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 20:17:50
	Avia McClain-Stocker	
	(b) (4)	

**US3052220**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'I'	System	21 Oct 2020 20:17:50

**US3052220**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:28:36
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:18:16

**US3052220**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:28:36
User entered '15 Oct 2020'	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:18:16

**US3052220**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[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 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4)	03 Dec 2020 19:28:36
User entered 'Clinic (Clinic)'	Avia McClain-Stocker	21 Oct 2020 20:18:16
	(b) (4)	

**US3052220**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'VISIT3'	System	21 Oct 2020 20:18:16

US3052220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:38
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:18:44

US3052220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:38
User entered '15 Oct 2020'	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:18:44



US3052220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:38
User entered '11:05'	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:18:44

**US3052220**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered '15 Oct 2020 11:05'	System	21 Oct 2020 20:18:44

US3052220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:38
User entered '97.9' F	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:18:44

US3052220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:38
User entered 'Oral (Oral)'	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:18:44

**US3052220**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:38
User entered empty.	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:18:44

US3052220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:38
User entered '68'	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:18:44

**US3052220**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'bpm'	System	21 Oct 2020 20:18:44

US3052220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:38
User entered '16'	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:18:44



US3052220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'breaths/min'	System	21 Oct 2020 20:18:44

US3052220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:38
User entered '134'	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:18:44

US3052220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'mmHg'	System	21 Oct 2020 20:18:44

US3052220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:38
User entered '82'	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:18:44

US3052220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'mmHg'	System	21 Oct 2020 20:18:44

**US3052220**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16

US3052220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16

US3052220

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:47
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:18:51



US3052220

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:53:47
User entered '15 Oct 2020'	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:18:51

US3052220

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:54:24
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:19:17

US3052220

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however corresponding sample collection date was not reported under visit 3 Day 57 visit in PPD Central lab. Please confirm and update the correct sample date in Preclarus PPD at this visit 3 Day 57 visit .' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 10:26:30
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however corresponding sample collection date was not reported under visit 3 Day 57 visit in PPD Central lab. Please confirm and update the correct sample date in Preclarus PPD at this visit 3 Day 57 visit .' answered with 'Confirmed date ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 18:41:04
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however corresponding sample collection date was not reported under visit 3 Day 57 visit in PPD Central lab. Please confirm and update the correct sample date in Preclarus PPD at this visit 3 Day 57 visit .' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 14:06:08
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' canceled (Site from DM).		08 Jan 2021 14:05:25
DataPoint Verified.		03 Dec 2020 19:54:24

US3052220

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). User entered '15 Oct 2020'	(b) (4), (b) (6)	03 Dec 2020 13:46:50
	Avia McClain-Stocker	21 Oct 2020 20:19:17
	(b) (4)	

**US3052220**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:29**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:54:24
User entered '11:29'	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:19:17

**US3052220**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered '15 Oct 2020 11:29'	System	21 Oct 2020 20:19:17

US3052220

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 19:54:29
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	21 Oct 2020 20:19:21

**US3052220**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered '1'	System	21 Oct 2020 20:19:21



**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 64'	System	14 Aug 2020 16:37:22

US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-10-16T10:47:48', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '35141eaf-f852-4be0-8cc1-ef2e7b9f0ea0'	System	16 Oct 2020 14:48:32
User entered 'No (N)'	System	16 Oct 2020 14:48:32

US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-10-16T10:48:07', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '35141eaf-f852-4be0-8cc1-ef2e7b9f0ea0'	System	16 Oct 2020 14:48:32
User entered 'No (N)'	System	16 Oct 2020 14:48:32

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-10-16T10:48:29', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '35141eaf-f852-4be0-8cc1-ef2e7b9f0ea0'	System	16 Oct 2020 14:48:32
User entered '16 Oct 2020 10:48:29'	System	16 Oct 2020 14:48:32

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
Data entry locked.	System	14 Aug 2020 16:37:22
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 16:37:22

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
Data entry locked.	System	14 Aug 2020 16:37:22
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 16:37:22

US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 71'	System	14 Aug 2020 16:37:22

US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 05:10:28
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'AE's already recorded for these dates, please see AEs' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 18:46:19
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 14:28:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-10-21T10:18:49', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'b81ad6fc-dce5-41de-8440-99074ab21911'	System	21 Oct 2020 14:20:28
User entered 'Yes (Y)'	System	21 Oct 2020 14:20:28



US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-10-21T10:18:43', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'b81ad6fc-dce5-41de-8440-99074ab21911'	System	21 Oct 2020 14:20:28
User entered 'No (N)'	System	21 Oct 2020 14:20:28

US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-10-21T10:18:56', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'b81ad6fc-dce5-41de-8440-99074ab21911'	System	21 Oct 2020 14:20:28
User entered 'No (N)'	System	21 Oct 2020 14:20:28

US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-10-21T10:19:39', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'b81ad6fc-dce5-41de-8440-99074ab21911'	System	21 Oct 2020 14:20:28
User entered 'Yes (Y)'	System	21 Oct 2020 14:20:28

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-10-21T10:19:44', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'b81ad6fc-dce5-41de-8440-99074ab21911'	System	21 Oct 2020 14:20:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Oct 2020 14:20:28

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-10-21T10:20:20', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'b81ad6fc-dce5-41de-8440-99074ab21911'	System	21 Oct 2020 14:20:28
User entered '21 Oct 2020 10:20:20'	System	21 Oct 2020 14:20:28

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
Data entry locked.	System	14 Aug 2020 16:37:22
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 16:37:22

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
Data entry locked.	System	14 Aug 2020 16:37:22
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 16:37:22

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 78'	System	14 Aug 2020 16:37:22



US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 05:10:23
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'AE's already recorded for these dates, please see AEs' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 18:46:27
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 14:28:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-10-28T18:44:34', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '1a7b96c6-1257-413a-bff4-6513868cd926'	System	28 Oct 2020 22:46:17
User entered 'Yes (Y)'	System	28 Oct 2020 22:46:17

US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-10-28T18:44:51', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '1a7b96c6-1257-413a-bff4-6513868cd926'	System	28 Oct 2020 22:46:17
User entered 'No (N)'	System	28 Oct 2020 22:46:17

US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-10-28T18:45:03', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '1a7b96c6-1257-413a-bff4-6513868cd926'	System	28 Oct 2020 22:46:17
User entered 'No (N)'	System	28 Oct 2020 22:46:17

US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-10-28T18:45:14', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '1a7b96c6-1257-413a-bff4-6513868cd926'	System	28 Oct 2020 22:46:17
User entered 'Yes (Y)'	System	28 Oct 2020 22:46:17

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-10-28T18:45:35', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '1a7b96c6-1257-413a-bff4-6513868cd926'	System	28 Oct 2020 22:46:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Oct 2020 22:46:17

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-10-28T18:46:08', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '1a7b96c6-1257-413a-bff4-6513868cd926'	System	28 Oct 2020 22:46:17
User entered '28 Oct 2020 18:46:08'	System	28 Oct 2020 22:46:17

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
Data entry locked.	System	14 Aug 2020 16:37:22
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 16:37:22

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
Data entry locked.	System	14 Aug 2020 16:37:22
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 16:37:22



US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 92'	System	14 Aug 2020 16:37:22

US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-11-11T10:09:20', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'c130392c-0c0a-4345-ac13-f9a4d5d6d1e3'	System	11 Nov 2020 15:09:45
User entered 'No (N)'	System	11 Nov 2020 15:09:45

US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-11-11T10:09:27', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'c130392c-0c0a-4345-ac13-f9a4d5d6d1e3'	System	11 Nov 2020 15:09:45
User entered 'No (N)'	System	11 Nov 2020 15:09:45

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-11-11T10:09:45', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'c130392c-0c0a-4345-ac13-f9a4d5d6d1e3'	System	11 Nov 2020 15:09:45
User entered '11 Nov 2020 10:09:45'	System	11 Nov 2020 15:09:45

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
Data entry locked.	System	14 Aug 2020 16:37:22
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 16:37:22

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
Data entry locked.	System	14 Aug 2020 16:37:22
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 16:37:22

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16
Data entry locked.	System	14 Aug 2020 16:37:22
User entered 'Day 99'	System	14 Aug 2020 16:37:22

US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16



US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16



**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16



**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

US3052220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16



**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16
Data entry locked.	System	14 Aug 2020 16:37:22
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 16:37:22

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:24:37
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:28:16
Data entry locked.	System	14 Aug 2020 16:37:22
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 16:37:22

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 07:28:16

US3052220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:29

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 04:53:39
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'AE captured- thyroid cancer' (Site from DM).	Avia McClain-Stocker	13 Apr 2021 20:43:03
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 14:54:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-11-19T09:35:12', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5792be73-2f2d-43ed-b0b7-7d23ebcedf59'	System	19 Nov 2020 14:36:34
User entered 'Yes (Y)'	System	19 Nov 2020 14:36:34

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2020-11-19T09:35:22', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5792be73-2f2d-43ed-b0b7-7d23ebcedf59'	System	19 Nov 2020 14:36:34
User entered 'No (N)'	System	19 Nov 2020 14:36:34

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2020-11-19T09:35:29', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5792be73-2f2d-43ed-b0b7-7d23ebcedf59'	System	19 Nov 2020 14:36:34
User entered 'No (N)'	System	19 Nov 2020 14:36:34

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2020-11-19T09:35:51', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5792be73-2f2d-43ed-b0b7-7d23ebcedf59'	System	19 Nov 2020 14:36:34
User entered 'Yes (Y)'	System	19 Nov 2020 14:36:34

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Please 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 (4bceb25c41e1ec43)', Time: '2020-11-19T09:36:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5792be73-2f2d-43ed-b0b7-7d23ebcedf59'	System	19 Nov 2020 14:36:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 14:36:34



**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-11-19T09:36:23', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5792be73-2f2d-43ed-b0b7-7d23ebcdf59'	System	19 Nov 2020 14:36:34
User entered '19 Nov 2020 09:36:23'	System	19 Nov 2020 14:36:34

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2020-11-22T14:49:41', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'ef6caf84-c2ee-4394-9fca-c30e09b15c8e'	System	22 Nov 2020 19:50:15
User entered 'No (N)'	System	22 Nov 2020 19:50:15

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2020-11-22T14:49:52', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'ef6caf84-c2ee-4394-9fca-c30e09b15c8e'	System	22 Nov 2020 19:50:15
User entered 'No (N)'	System	22 Nov 2020 19:50:15

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-11-22T14:50:13', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'ef6caf84-c2ee-4394-9fca-c30e09b15c8e'	System	22 Nov 2020 19:50:15
User entered '22 Nov 2020 14:50:13'	System	22 Nov 2020 19:50:15

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:28:16



**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2020-11-29T16:22:34', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '2076f528-57ee-440a-adb0-63772a1264fb'	System	29 Nov 2020 21:23:17
User entered 'No (N)'	System	29 Nov 2020 21:23:17

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2020-11-29T16:22:41', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '2076f528-57ee-440a-adb0-63772a1264fb'	System	29 Nov 2020 21:23:17
User entered 'No (N)'	System	29 Nov 2020 21:23:17

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-11-29T16:23:13', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '2076f528-57ee-440a-adb0-63772a1264fb' User entered '29 Nov 2020 16:23:13'	System	29 Nov 2020 21:23:17
	System	29 Nov 2020 21:23:17

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:28:16



**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2020-12-07T19:47:29', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5edc4de6-71d4-40cb-953d-7302b1a69888'	System	08 Dec 2020 00:48:05
User entered 'No (N)'	System	08 Dec 2020 00:48:05

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2020-12-07T19:47:37', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5edc4de6-71d4-40cb-953d-7302b1a69888'	System	08 Dec 2020 00:48:05
User entered 'No (N)'	System	08 Dec 2020 00:48:05

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-12-07T19:48:06', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5edc4de6-71d4-40cb-953d-7302b1a69888'	System	08 Dec 2020 00:48:05
User entered '07 Dec 2020 19:48:06'	System	08 Dec 2020 00:48:05

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2020-12-13T12:51:19', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '37fbc01c-1bcc-46ac-8ebe-6ee1fb2ae93c'	System	13 Dec 2020 17:51:46
User entered 'No (N)'	System	13 Dec 2020 17:51:46

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2020-12-13T12:51:28', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '37fbc01c-1bcc-46ac-8ebe-6ee1fb2ae93c'	System	13 Dec 2020 17:51:46
User entered 'No (N)'	System	13 Dec 2020 17:51:46



**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-12-13T12:51:45', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '37fbc01c-1bcc-46ac-8ebe-6ee1fb2ae93c'	System	13 Dec 2020 17:51:46
User entered '13 Dec 2020 12:51:45'	System	13 Dec 2020 17:51:46

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2020-12-23T00:08:02', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'a7f004d5-245a-4ddf-b1f6-973c7d5b471b'	System	23 Dec 2020 05:08:27
User entered 'No (N)'	System	23 Dec 2020 05:08:27

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2020-12-23T00:08:11', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'a7f004d5-245a-4ddf-b1f6-973c7d5b471b'	System	23 Dec 2020 05:08:27
User entered 'No (N)'	System	23 Dec 2020 05:08:27

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-12-23T00:08:28', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'a7f004d5-245a-4ddf-b1f6-973c7d5b471b'	System	23 Dec 2020 05:08:27
User entered '23 Dec 2020 00:08:28'	System	23 Dec 2020 05:08:27

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:28:16



**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2020-12-28T09:45:37', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '60d1b2ed-5c5a-410d-96d9-8c28e12482db'	System	28 Dec 2020 14:46:04
User entered 'No (N)'	System	28 Dec 2020 14:46:04

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2020-12-28T09:45:46', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '60d1b2ed-5c5a-410d-96d9-8c28e12482db'	System	28 Dec 2020 14:46:04
User entered 'No (N)'	System	28 Dec 2020 14:46:04

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2020-12-28T09:46:01', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '60d1b2ed-5c5a-410d-96d9-8c28e12482db'	System	28 Dec 2020 14:46:04
User entered '28 Dec 2020 09:46:01'	System	28 Dec 2020 14:46:04

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:28:16



**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-01-03T11:44:13', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5f3cba78-14bb-4f5b-b9bd-a5b86bb3b8fb'	System	03 Jan 2021 16:44:46
User entered 'No (N)'	System	03 Jan 2021 16:44:46

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2021-01-03T11:44:24', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5f3cba78-14bb-4f5b-b9bd-a5b86bb3b8fb'	System	03 Jan 2021 16:44:46
User entered 'No (N)'	System	03 Jan 2021 16:44:46

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-01-03T11:44:48', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5f3cba78-14bb-4f5b-b9bd-a5b86bb3b8fb' User entered '03 Jan 2021 11:44:48'	System	03 Jan 2021 16:44:46
	System	03 Jan 2021 16:44:46

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-01-12T13:45:55', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5f4bff62-c49c-4e49-a1b8-c03c170e9dd5'	System	12 Jan 2021 18:47:26
User entered 'Yes (Y)'	System	12 Jan 2021 18:47:26

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2021-01-12T13:46:02', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5f4bff62-c49c-4e49-a1b8-c03c170e9dd5'	System	12 Jan 2021 18:47:26
User entered 'No (N)'	System	12 Jan 2021 18:47:26



**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-01-12T13:46:12', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5f4bff62-c49c-4e49-a1b8-c03c170e9dd5'	System	12 Jan 2021 18:47:26
User entered 'No (N)'	System	12 Jan 2021 18:47:26

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-01-12T13:46:27', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5f4bff62-c49c-4e49-a1b8-c03c170e9dd5'	System	12 Jan 2021 18:47:26
User entered 'Yes (Y)'	System	12 Jan 2021 18:47:26

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Please 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 (4bceb25c41e1ec43)', Time: '2021-01-12T13:46:42', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5f4bff62-c49c-4e49-a1b8-c03c170e9dd5'	System	12 Jan 2021 18:47:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Jan 2021 18:47:26

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-01-12T13:47:15', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '5f4bff62-c49c-4e49-a1b8-c03c170e9dd5'	System	12 Jan 2021 18:47:26
User entered '12 Jan 2021 13:47:15'	System	12 Jan 2021 18:47:26

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-01-18T13:42:07', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '304e345d-09f2-4ced-9b5b-a6cf8d27bc90'	System	18 Jan 2021 18:42:38
User entered 'No (N)'	System	18 Jan 2021 18:42:38



**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2021-01-18T13:42:19', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '304e345d-09f2-4ced-9b5b-a6cf8d27bc90'	System	18 Jan 2021 18:42:38
User entered 'No (N)'	System	18 Jan 2021 18:42:38

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-01-18T13:42:40', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '304e345d-09f2-4ced-9b5b-a6cf8d27bc90'	System	18 Jan 2021 18:42:38
User entered '18 Jan 2021 13:42:40'	System	18 Jan 2021 18:42:38

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-01-24T21:31:45', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '6a1ec13b-e01d-47ce-be8c-8b0e149def67'	System	25 Jan 2021 02:33:01
User entered 'No (N)'	System	25 Jan 2021 02:33:01

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2021-01-24T21:31:56', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '6a1ec13b-e01d-47ce-be8c-8b0e149def67'	System	25 Jan 2021 02:33:01
User entered 'No (N)'	System	25 Jan 2021 02:33:01

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-01-24T21:33:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '6a1ec13b-e01d-47ce-be8c-8b0e149def67'	System	25 Jan 2021 02:33:01
User entered '24 Jan 2021 21:33:00'	System	25 Jan 2021 02:33:01



**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-02-01T10:36:40', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'b20ef08f-59b3-4363-9a2f-8679be560302'	System	01 Feb 2021 15:37:02
User entered 'No (N)'	System	01 Feb 2021 15:37:02

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2021-02-01T10:36:46', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'b20ef08f-59b3-4363-9a2f-8679be560302'	System	01 Feb 2021 15:37:02
User entered 'No (N)'	System	01 Feb 2021 15:37:02

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-02-01T10:37:01', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'b20ef08f-59b3-4363-9a2f-8679be560302'	System	01 Feb 2021 15:37:02
User entered '01 Feb 2021 10:37:01'	System	01 Feb 2021 15:37:02

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:28:16



**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-02-07T23:22:16', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '44c4f958-b699-405a-bd99-a9602023ae93'	System	08 Feb 2021 04:22:39
User entered 'No (N)'	System	08 Feb 2021 04:22:39

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2021-02-07T23:22:24', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '44c4f958-b699-405a-bd99-a9602023ae93'	System	08 Feb 2021 04:22:39
User entered 'No (N)'	System	08 Feb 2021 04:22:39

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-02-07T23:22:38', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '44c4f958-b699-405a-bd99-a9602023ae93'	System	08 Feb 2021 04:22:39
User entered '07 Feb 2021 23:22:38'	System	08 Feb 2021 04:22:39

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-02-15T17:08:49', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '9aa40f2d-93b9-437a-bdf3-0d024dd423de'	System	15 Feb 2021 22:09:25
User entered 'No (N)'	System	15 Feb 2021 22:09:25



**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2021-02-15T17:08:57', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '9aa40f2d-93b9-437a-bdf3-0d024dd423de'	System	15 Feb 2021 22:09:25
User entered 'No (N)'	System	15 Feb 2021 22:09:25

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-02-15T17:09:24', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '9aa40f2d-93b9-437a-bdf3-0d024dd423de' User entered '15 Feb 2021 17:09:24'	System	15 Feb 2021 22:09:25
	System	15 Feb 2021 22:09:25

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-02-25T12:00:48-05:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '74ea3793-9228-4901-a586-5cb78fdbd57c' User entered 'No (N)'	System	26 Feb 2021 00:30:28
	System	26 Feb 2021 00:30:28

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2021-02-25T12:00:55-05:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '74ea3793-9228-4901-a586-5cb78fdbd57c' User entered 'No (N)'	System	26 Feb 2021 00:30:28
	System	26 Feb 2021 00:30:28

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-02-25T12:01:22-05:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '74ea3793-9228-4901-a586-5cb78fdbd57c' User entered '25 Feb 2021 12:01:22'	System	26 Feb 2021 00:30:28
	System	26 Feb 2021 00:30:28



**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-03-01T14:01:26-05:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '1ed8d5bb-ab4d-44ad-b552-0d9940819560'	System	01 Mar 2021 19:02:12
User entered 'No (N)'	System	01 Mar 2021 19:02:12

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2021-03-01T14:01:34-05:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '1ed8d5bb-ab4d-44ad-b552-0d9940819560'	System	01 Mar 2021 19:02:12
User entered 'No (N)'	System	01 Mar 2021 19:02:12

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-03-01T14:01:51-05:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '1ed8d5bb-ab4d-44ad-b552-0d9940819560'	System	01 Mar 2021 19:02:12
User entered '01 Mar 2021 14:01:51'	System	01 Mar 2021 19:02:12

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:28:16



**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-03-09T16:33:02-05:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '573ef584-dfeb-40d0-a9d6-8945dcf09153'	System	09 Mar 2021 21:33:34
User entered 'No (N)'	System	09 Mar 2021 21:33:34

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2021-03-09T16:33:21-05:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '573ef584-dfeb-40d0-a9d6-8945dcf09153'	System	09 Mar 2021 21:33:34
User entered 'No (N)'	System	09 Mar 2021 21:33:34

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-03-09T16:33:33-05:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '573ef584-dfeb-40d0-a9d6-8945dcf09153' User entered '09 Mar 2021 16:33:33'	System	09 Mar 2021 21:33:34
	System	09 Mar 2021 21:33:34

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-03-14T12:50:54-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '6865dd59-c886-4ad7-9f56-a4d7675bbb19'	System	14 Mar 2021 16:51:25
User entered 'No (N)'	System	14 Mar 2021 16:51:25



**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2021-03-14T12:51:02-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '6865dd59-c886-4ad7-9f56-a4d7675bbb19'	System	14 Mar 2021 16:51:25
User entered 'No (N)'	System	14 Mar 2021 16:51:25

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-03-14T12:51:22-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '6865dd59-c886-4ad7-9f56-a4d7675bbb19' User entered '14 Mar 2021 12:51:22'	System	14 Mar 2021 16:51:25
	System	14 Mar 2021 16:51:25

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:28:16

**US3052220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-03-21T11:31:24-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'b321fece-cc6b-40e1-8b91-cf121f2401cb' User entered 'No (N)'	System	21 Mar 2021 15:32:18
	System	21 Mar 2021 15:32:18

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2021-03-21T11:31:34-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'b321fece-cc6b-40e1-8b91-cf121f2401cb' User entered 'No (N)'	System	21 Mar 2021 15:32:18

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-03-21T11:32:15-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'b321fece-cc6b-40e1-8b91-cf121f2401cb' User entered '21 Mar 2021 11:32:15'	System	21 Mar 2021 15:32:18
	System	21 Mar 2021 15:32:18



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-03-30T15:06:54-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '7157defe-f16e-4704-bbe9-6f2c7563b736'	System	30 Mar 2021 19:10:17
User entered 'No (N)'	System	30 Mar 2021 19:10:17

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2021-03-30T15:07:20-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '7157defe-f16e-4704-bbe9-6f2c7563b736'	System	30 Mar 2021 19:10:17
User entered 'No (N)'	System	30 Mar 2021 19:10:17

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-03-30T15:07:46-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '7157defe-f16e-4704-bbe9-6f2c7563b736'	System	30 Mar 2021 19:10:17
User entered '30 Mar 2021 15:07:46'	System	30 Mar 2021 19:10:17

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-04-05T20:30:28-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '53c8655c-9861-405a-8606-3189ad719bb9'	System	06 Apr 2021 00:32:42
User entered 'No (N)'	System	06 Apr 2021 00:32:42

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2021-04-05T20:30:36-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '53c8655c-9861-405a-8606-3189ad719bb9' User entered 'No (N)'	System	06 Apr 2021 00:32:42

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-04-05T20:32:41-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '53c8655c-9861-405a-8606-3189ad719bb9'	System	06 Apr 2021 00:32:42
User entered '05 Apr 2021 20:32:41'	System	06 Apr 2021 00:32:42

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-04-12T09:47:04-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '841b6d8e-0919-415b-9c3a-055a5fde05ab' User entered 'No (N)'	System	12 Apr 2021 13:47:37
	System	12 Apr 2021 13:47:37



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2021-04-12T09:47:14-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '841b6d8e-0919-415b-9c3a-055a5fde05ab'	System	12 Apr 2021 13:47:37
User entered 'No (N)'	System	12 Apr 2021 13:47:37

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-04-12T09:47:35-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '841b6d8e-0919-415b-9c3a-055a5fde05ab' User entered '12 Apr 2021 09:47:35'	System	12 Apr 2021 13:47:37
	System	12 Apr 2021 13:47:37

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-04-18T15:00:45-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '7f632a49-106a-4eed-9d91-80fb43b59c89'	System	18 Apr 2021 19:01:16
User entered 'No (N)'	System	18 Apr 2021 19:01:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2021-04-18T15:00:54-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '7f632a49-106a-4eed-9d91-80fb43b59c89'	System	18 Apr 2021 19:01:16
User entered 'No (N)'	System	18 Apr 2021 19:01:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-04-18T15:01:10-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '7f632a49-106a-4eed-9d91-80fb43b59c89'	System	18 Apr 2021 19:01:16
User entered '18 Apr 2021 15:01:10'	System	18 Apr 2021 19:01:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-04-26T13:59:20-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'f6db26dc-4540-4ff2-9f39-345ddee1dfea' User entered 'No (N)'	System	26 Apr 2021 18:00:19
	System	26 Apr 2021 18:00:19

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2021-04-26T13:59:45-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'f6db26dc-4540-4ff2-9f39-345ddee1dfea' User entered 'No (N)'	System	26 Apr 2021 18:00:19

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-04-26T14:00:11-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: 'f6db26dc-4540-4ff2-9f39-345ddee1dfea' User entered '26 Apr 2021 14:00:11'	System	26 Apr 2021 18:00:19
	System	26 Apr 2021 18:00:19

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[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 (4bceb25c41e1ec43)', Time: '2021-05-03T12:03:40-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '6e97ec04-8972-452f-8373-b856ea948e3e'	System	03 May 2021 16:12:08
User entered 'No (N)'	System	03 May 2021 16:12:08

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

Have you been exposed to someone with 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 (4bceb25c41e1ec43)', Time: '2021-05-03T12:03:49-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '6e97ec04-8972-452f-8373-b856ea948e3e'	System	03 May 2021 16:12:08
User entered 'No (N)'	System	03 May 2021 16:12:08

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-05-03T12:04:03-04:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '6e97ec04-8972-452f-8373-b856ea948e3e'	System	03 May 2021 16:12:08
User entered '03 May 2021 12:04:03'	System	03 May 2021 16:12:08

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:28:16



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:28:16



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:28:16



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:28:16



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:28:16



**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:28:16

**US3052220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:28:16
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:28:16

US3052220

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:56:29**

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)	04 May 2021 03:48:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-03-01T14:02:01-05:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '9a1b15fa-9ee4-48d9-9ce4-b80a318bfbd1'	System	01 Mar 2021 19:02:26
User entered 'No (N)'	System	01 Mar 2021 19:02:26

**US3052220**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:48:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4bceb25c41e1ec43)', Time: '2021-03-01T14:02:11-05:00', User OID: 'PatientReportedOutcome (US3052220)', ODM File OID: '9a1b15fa-9ee4-48d9-9ce4-b80a318bfbd1'	System	01 Mar 2021 19:02:26
User entered '01 Mar 2021 14:02:11'	System	01 Mar 2021 19:02:26

**US3052220**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:20:37
User entered 'Yes (Y)'		19 Nov 2020 13:12:25

**US3052220**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:20:37
User entered '13 Nov 2020'		19 Nov 2020 13:12:25

**US3052220**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:20:37
User entered 'Contact Made (CONTACT MADE)'		19 Nov 2020 13:12:25

US3052220

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:20:37
User entered empty.		19 Nov 2020 13:12:25



**US3052220**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:20:45
User entered 'Yes (Y)'		16 Dec 2020 21:47:53

**US3052220**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:16
User entered 'I'	System	16 Dec 2020 21:47:53

US3052220

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:46
DataPoint Verified.		05 Apr 2021 16:19:19
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 21:48:23

US3052220

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:46
DataPoint Verified.		05 Apr 2021 16:19:19
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 21:48:23

US3052220

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:46
DataPoint Verified.		05 Apr 2021 16:19:19
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 21:48:23

US3052220

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:46
DataPoint Verified.		05 Apr 2021 16:19:19
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 21:48:23

US3052220

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:46
DataPoint Verified.		05 Apr 2021 16:19:22
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	04 Jan 2021 01:49:24

**US3052220**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:46
User entered 'I'	System	04 Jan 2021 01:49:24



US3052220

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:46
DataPoint Verified.		15 Apr 2021 16:41:28
User closed query 'Please provide source.' (Site from CRA).		15 Apr 2021 16:41:26
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
Query 'Please provide source.' answered with 'not done' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:29:57
Signature has been broken.		14 Apr 2021 18:29:36
User entered 'No (N)' reason for change: Data Entry Error		14 Apr 2021 18:29:36
User opened query 'Please provide source.' (Site from CRA).		05 Apr 2021 16:21:27
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 21:30:36

US3052220

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:46
DataPoint Verified.		15 Apr 2021 16:41:28
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:29:36
User entered empty; reason for change Data Entry Error		14 Apr 2021 18:29:36
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 21:30:36

US3052220

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:46
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:28
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:29:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 18:29:36
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 21:30:36

US3052220

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:46
DataPoint Verified.		15 Apr 2021 16:41:28
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 21:30:36

US3052220

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:46
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:21:31
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:42:49
User closed query 'Per CDM: 'Is the participant continuing to the next visit?' is yes, however safety call 149 (1) is not completed. Kindly review and update accordingly. Thank you.' (Site from DM).	(b) (4)	
Query 'Per CDM: 'Is the participant continuing to the next visit?' is yes, however safety call 149 (1) is not completed. Kindly review and update accordingly. Thank you.' answered with 'subject continuing ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 14:30:18
User opened query 'Per CDM: 'Is the participant continuing to the next visit?' is yes, however safety call 149 (1) is not completed. Kindly review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 21:31:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 18:06:02
	(b) (4), (b) (6)	25 Feb 2021 15:11:57

**US3052220**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:46
User entered 'I'	System	25 Feb 2021 15:11:57

US3052220

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:46
DataPoint Verified.		05 Apr 2021 16:21:47
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:12:12

**US3052220**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:46
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:21:47
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:12:12



**US3052220**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:46
DataPoint Verified.		05 Apr 2021 16:21:47
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:12:12

**US3052220**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:46
DataPoint Verified.		05 Apr 2021 16:21:47
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:12:12

US3052220

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:46
DataPoint Verified.		05 Apr 2021 16:21:50
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:44:10

**US3052220**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:50:46
User entered 'I'	System	26 Feb 2021 18:44:10

US3052220

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
User closed query 'Per CDM: Please complete the immunogenecity assessment form as Yes or No. Otherwise clarify. thank you.' (Site from DM).		09 Apr 2021 21:54:37
User closed query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.' (Site from DM).		09 Apr 2021 21:54:35
Query 'Per CDM: Please complete the immunogenecity assessment form as Yes or No. Otherwise clarify. thank you.' answered with 'updated' (Site from DM).		06 Apr 2021 21:48:24
Query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.' answered with 'updated' (Site from DM).		06 Apr 2021 21:48:19
DataPoint Verified.		05 Apr 2021 16:22:22
User opened query 'Per CDM: Please complete the immunogenecity assessment form as Yes or No. Otherwise clarify. thank you.' (Site from DM).		30 Mar 2021 12:37:43
User opened query 'Per CDM: Visit 4 Day 209 and OL-D29 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-29 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.' (Site from DM).		30 Mar 2021 12:36:53
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:44:38

US3052220

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:22:22
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	01 Mar 2021 18:07:50
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'confirmed visit date is 2/25/2021' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 18:45:07
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	26 Feb 2021 18:44:38
User entered '25 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 18:44:38

US3052220

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:29

[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 12:32:42
DataPoint Verified.		05 Apr 2021 16:22:22
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:44:38

**US3052220**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
User entered 'VISIT4'	System	26 Feb 2021 18:44:38



**US3052220**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:24:16
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 21:45:53

US3052220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:24:16
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered '25 Feb 2021'	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 21:45:53

**US3052220**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:24:16
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered '11:53'	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 21:45:53

**US3052220**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
User entered '25 Feb 2021 11:53'	System	30 Mar 2021 21:45:53

US3052220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:24:16
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered '36.5' C	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 21:45:53

**US3052220**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:24:16
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered 'Oral (Oral)'	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 21:45:53

**US3052220**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:24:16
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 21:45:53

**US3052220**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:24:16
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered '70'	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 21:45:53



US3052220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
User entered 'bpm'	System	30 Mar 2021 21:45:53

US3052220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:24:16
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered '16'	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 21:45:53

US3052220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
User entered 'breaths/min'	System	30 Mar 2021 21:45:53

US3052220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:24:16
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered '135'	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 21:45:53

US3052220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
User entered 'mmHg'	System	30 Mar 2021 21:45:53

US3052220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:24:16
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered '88'	(b) (4) amy sheets (b) (4) (b) (4)	30 Mar 2021 21:45:53

US3052220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
User entered 'mmHg'	System	30 Mar 2021 21:45:53

**US3052220**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42



US3052220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42

**US3052220**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:56:29**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:24:29
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:45:16

US3052220

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
DataPoint Verified.		05 Apr 2021 16:24:29
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:45:16

**US3052220**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:24:41
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:04:17

US3052220

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25FEB2021 is recorded under Visit 4 Day 209 visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you '(Site from DM).		19 Apr 2021 08:16:05
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25FEB2021 is recorded under Visit 4 Day 209 visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you ' answered with 'emailed req to ppd. accession # 1F617471595 shipped on march 09,2021 tracking # 992065942872' (Site from DM).		08 Apr 2021 18:11:27
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25FEB2021 is recorded under Visit 4 Day 209 visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you '(Site from DM).	(b) (4), (b) (6)	08 Apr 2021 08:56:24
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:24:41
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:04:17

**US3052220**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:29**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:24:41
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered '13:45'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:04:17

**US3052220**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
User entered '25 Feb 2021 13:45'	System	31 Mar 2021 16:04:17

**US3052220**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:24:44
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:45:22



**US3052220**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:32:42
User entered 'I'	System	26 Feb 2021 18:45:22

**US3052220**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:25:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:49

**US3052220**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:25:17
User entered '16 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:49

**US3052220**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:25:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:49

US3052220

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:25:17
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 13:49:49

**US3052220**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:25:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:54

**US3052220**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 13:49:54

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:09:25
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:48:06



**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:09:25
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:48:06

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:09:25
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:48:06

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'UNBLND_DECIDE'	System	27 Jan 2021 15:48:06

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:56:29

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:09:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:48:38

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:56:29**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:01:49

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:56:29

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:09:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:48:38

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:56:29**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:01:49

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:56:29

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:09:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:48:38



US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:56:29

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:09:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:48:38

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:56:29**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:09:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:48:38

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:56:29**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:09:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:48:38

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:56:29

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:09:48
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:48:38

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:56:29**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered '1'	System	27 Jan 2021 15:48:38

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'I'	System	27 Jan 2021 15:48:38

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '175' cm	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '102' kg	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46



US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered '33.30612'	System	27 Jan 2021 15:53:46
DataPoint set to visible.	System	27 Jan 2021 15:48:38

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 14:56:29**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '175' cm	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 14:56:29**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '102' kg	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered '33.30612'	System	27 Jan 2021 15:53:46
DataPoint set to visible.	System	27 Jan 2021 15:48:38

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User accepted default value 'Pre-Dose (PREDOSE)'		27 Jan 2021 15:53:46

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '14:27'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46



**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered '26 Jan 2021 14:27'	System	27 Jan 2021 15:53:46

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '87'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'bpm'	System	27 Jan 2021 15:53:46

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '12'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'breaths/min'	System	27 Jan 2021 15:53:46



US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '124'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'mmHg'	System	27 Jan 2021 15:53:46

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '81'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'mmHg'	System	27 Jan 2021 15:53:46

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '175' cm	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 14:56:29**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '102' kg	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered '33.30612'	System	27 Jan 2021 15:53:46
DataPoint set to visible.	System	27 Jan 2021 15:48:38

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User accepted default value 'Post-Dose (POSTDOSE)'		27 Jan 2021 15:53:46



**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '16:15'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered '26 Jan 2021 16:15'	System	27 Jan 2021 15:53:46

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	(b) (4)	15 Mar 2021 17:36:19
User entered empty.	(b) (4), (b) (6)	27 Jan 2021 15:53:46

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '65'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46



US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'bpm'	System	27 Jan 2021 15:53:46

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '14'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'breaths/min'	System	27 Jan 2021 15:53:46

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '124'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'mmHg'	System	27 Jan 2021 15:53:46

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:13
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '80'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:53:46

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'mmHg'	System	27 Jan 2021 15:53:46

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:19
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:54:31



US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:19
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:54:31

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:31
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:55:15

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:31
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:55:15

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

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)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:31
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:55:15

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'mRNA-1273'	System	27 Jan 2021 15:55:15
DataPoint set to visible.	System	27 Jan 2021 15:48:38

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:31
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:55:15

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:56:29**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:31
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '15:40'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:55:15

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:56:29**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered '26 Jan 2021 15:40'	System	27 Jan 2021 15:55:15



US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:31
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:55:15

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:56:29**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:31
User entered 'ONCE'	System	27 Jan 2021 15:55:15

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:56:29**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'INTRAMUSCULAR'	System	27 Jan 2021 15:55:15

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:11:39
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User closed query 'Per GCL Lab Reconciliation: Immuno requery: Thank you for the Accession number. Please provide the tracking number as well. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 12:38:37
Query 'Per GCL Lab Reconciliation: Immuno requery: Thank you for the Accession number. Please provide the tracking number as well. ' answered with '1F638149843 bar code ID' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 19:42:22
User opened query 'Per GCL Lab Reconciliation: Immuno requery: Thank you for the Accession number. Please provide the tracking number as well. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 20:15:59
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 26JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 20:15:59
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 26JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate.' answered with 'sample shipped. Accession number 1F638149843' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 18:43:15
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 26JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 14:36:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 15:55:31

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:39
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:55:31

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:29**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:39
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '15:32'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:55:31

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered '26 Jan 2021 15:32'	System	27 Jan 2021 15:55:31

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:56:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:08:52
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:55:53



**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:56:29**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:08:52
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:55:53

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:56:29**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:08:52
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '15:34'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:55:53

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:56:29**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered '26 Jan 2021 15:34'	System	27 Jan 2021 15:55:53

US3052220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:11:45
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:56:01

**US3052220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'I'	System	27 Jan 2021 15:56:01

**US3052220**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:10
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:18:35
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:32:54

**US3052220**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:10
DataPoint Verified.		05 Apr 2021 16:18:35
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:32:54

**US3052220**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:10
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:18:35
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:32:54



**US3052220**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:10
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:18:35
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:32:54

US3052220

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:10
DataPoint Verified.		05 Apr 2021 16:18:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:33:04

**US3052220**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:10
User entered 'I'	System	05 Feb 2021 15:33:04

**US3052220**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:10
User entered '1'	System	05 Feb 2021 15:33:04
DataPoint set to visible.	System	05 Feb 2021 15:33:04

US3052220

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:13:17
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:45:55

**US3052220**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:13:17
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:45:55

**US3052220**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:13:17
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:45:55

**US3052220**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'OLD29'	System	26 Feb 2021 18:45:55



**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User accepted default value 'Pre-Dose (PREDOSE)'		26 Feb 2021 18:48:15

US3052220

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:01
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:15

US3052220

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:01
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:15

**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:29**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:01
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '11:53'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:15

**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered '25 Feb 2021 11:53'	System	26 Feb 2021 18:48:15

US3052220

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:01
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:15

**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:01
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:15

**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:01
User signature succeeded.	(b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 18:48:15



**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:01
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '70'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:15

**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'bpm'	System	26 Feb 2021 18:48:15

US3052220

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:14:01
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '16'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:15

US3052220

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'breaths/min'	System	26 Feb 2021 18:48:15

**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:14:01
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '135'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:15

**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'mmHg'	System	26 Feb 2021 18:48:15

US3052220

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:01
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '88'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:15

**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'mmHg'	System	26 Feb 2021 18:48:15



**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	26 Feb 2021 18:48:15

**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:14:01
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:15

**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:01
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:15

**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:01
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '13:02'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:15

**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered '25 Feb 2021 13:02'	System	26 Feb 2021 18:48:15

US3052220

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:01
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:15

**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:01
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:15

**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:01
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:15



**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:01
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '75'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:15

**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'bpm'	System	26 Feb 2021 18:48:15

US3052220

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:01
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '15'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:15

US3052220

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'breaths/min'	System	26 Feb 2021 18:48:15

US3052220

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:01
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '129'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:15

**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'mmHg'	System	26 Feb 2021 18:48:15

US3052220

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:01
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '93'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:15

**US3052220**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'mmHg'	System	26 Feb 2021 18:48:15



US3052220

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:22

**US3052220**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:56:29**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:22

US3052220

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:31
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:43

US3052220

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:31
User signature succeeded.	(b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 18:48:43

US3052220

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

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)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:31
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:43

**US3052220**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:56:29**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'mRNA-1273'	System	26 Feb 2021 18:48:43
DataPoint set to visible.	System	05 Feb 2021 15:33:04

US3052220

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:31
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:43

US3052220

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:31
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '12:27'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:43



**US3052220**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:56:29**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered '25 Feb 2021 12:27'	System	26 Feb 2021 18:48:43

US3052220

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:14:31
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:43

**US3052220**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:56:29**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:31
User entered 'ONCE'	System	26 Feb 2021 18:48:43

US3052220

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 18:48:43

**US3052220**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.		05 Apr 2021 16:14:34
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:48:47

**US3052220**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'I'	System	26 Feb 2021 18:48:47

US3052220

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:10
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:15:29
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:42:49
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	15 Mar 2021 23:38:41
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	14 Mar 2021 21:31:56
User entered 'No (N)'	(b) (4), (b) (6)	14 Mar 2021 21:31:56

**US3052220**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:10
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:15:29
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:42:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 21:31:56



**US3052220**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:10
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:15:29
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:42:49
User entered empty; reason for change Data Entry Error	(b) (4)	
	amy sheets (b) (4)	15 Mar 2021 23:38:41
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	14 Mar 2021 21:31:56

**US3052220**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:10
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:15:29
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:42:49
User entered 'missed'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 21:31:56

US3052220

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:15:31
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Mar 2021 21:32:08

**US3052220**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'I'	System	14 Mar 2021 21:32:08

**US3052220**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:16:04
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 18:42:01

**US3052220**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:16:04
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:42:01

**US3052220**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:16:04
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:42:01

**US3052220**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered 'OLD57'	System	25 Mar 2021 18:42:01



**US3052220**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:16:17
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 18:42:18

**US3052220**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:16:17
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 18:42:18

**US3052220**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:16:17
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 18:42:18

**US3052220**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered empty.	System	25 Mar 2021 18:42:18

**US3052220**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:16:17
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 18:42:18

**US3052220**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:16:17
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 18:42:18

**US3052220**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:16:17
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 18:42:18

**US3052220**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:16:17
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 18:42:18



**US3052220**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered empty.	System	25 Mar 2021 18:42:18

**US3052220**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:16:17
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 18:42:18

US3052220

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered empty.	System	25 Mar 2021 18:42:18

**US3052220**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:16:17
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 18:42:18

**US3052220**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered empty.	System	25 Mar 2021 18:42:18

**US3052220**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:16:17
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 18:42:18

US3052220

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered empty.	System	25 Mar 2021 18:42:18

**US3052220**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:29**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08



US3052220

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08

**US3052220**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:56:29**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:16:26
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 18:42:38

**US3052220**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:56:29**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:16:26
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 18:42:38

**US3052220**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:16:35
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:42:49

**US3052220**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:29**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:16:35
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered '23 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 18:42:49

**US3052220**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:29**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:16:35
User signature succeeded.	Yaa Oppong (b) (4)	01 Apr 2021 17:33:06
User entered '12:06'	(b) (4), (b) (6)	25 Mar 2021 18:42:49

**US3052220**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:46:08
User entered '23 Mar 2021 12:06'	System	25 Mar 2021 18:42:49

US3052220

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:56:29

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:41
User closed query 'Please provide AE log source.' (Site from CRA).	(b) (4)	19 Apr 2021 20:19:08
Query 'Please provide AE log source.' answered with 'updated Ae log source' (Site from CRA).	Avia McClain-Stocker	13 Apr 2021 20:28:57
User opened query 'Please provide AE log source.' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 16:34:18
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User closed query 'Please note that AE log is not provided in source. Also previous query "Per source, subject received a diagnosis of Thyroid Cancer on 23 Oct 2020. Please review source and create an AE for this diagnosis as appropriate." was not answered appropriately as it is still recorded but still not entered in EDC.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 20:32:45
Query 'Please note that AE log is not provided in source. Also previous query "Per source, subject received a diagnosis of Thyroid Cancer on 23 Oct 2020. Please review source and create an AE for this diagnosis as appropriate." was not answered appropriately as it is still recorded but still not entered in EDC.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Feb 2021 19:41:06
User opened query 'Please note that AE log is not provided in source. Also previous query "Per source, subject received a diagnosis of Thyroid Cancer on 23 Oct 2020. Please review source and create an AE for this diagnosis as appropriate." was not answered appropriately as it is still recorded but still not entered in EDC.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 15:39:21
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 15:26:17
User closed query 'Per source, subject received a diagnosis of Thyroid Cancer on 23 Oct 2020. Please review source and create an AE for this diagnosis as appropriate.' (Site from CRA).	(b) (4), (b) (6)	21 Feb 2021 05:08:14



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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:56:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per source, subject received a diagnosis of Thyroid Cancer on 23 Oct 2020. Please review source and create an AE for this diagnosis as appropriate.' answered with 'reviewed and updated' (Site from CRA).	(b) (4), (b) (6)	15 Feb 2021 18:43:47
User opened query 'Per source, subject received a diagnosis of Thyroid Cancer on 23 Oct 2020. Please review source and create an AE for this diagnosis as appropriate.' (Site from CRA).		03 Dec 2020 19:40:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Nicole Davis (b) (4)	16 Oct 2020 13:25:17
User entered 'No (N)'	(b) (4)	
	amy sheets (b) (4)	19 Aug 2020 19:14:27
	(b) (4)	

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenitis, LLT: Lymphadenitis - version MedDRA\23.0.	Coder Import (b) (4)	19 Mar 2021 07:07:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Mar 2021 07:07:52
User closed query 'Per CDM, DM CLR re-query: Response "Left lobe" is noted. Please update the Adverse event name to reflect your response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:39:50
Data point term sent to Coder	System	26 Feb 2021 19:11:31
Query 'Per CDM, DM CLR re-query: Response "Left lobe" is noted. Please update the Adverse event name to reflect your response. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 19:11:20
Coding entries removed.		26 Feb 2021 19:11:11
User entered 'LEFT SIDED LYMPHADENITIS of the salivary gland' reason for change: Data Entry Error		26 Feb 2021 19:11:11
User closed query 'Per DM CLR: Please review AE and please update to specify the location of Left Sided Lymphadenitis. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).		16 Feb 2021 08:58:07
User opened query 'Per CDM, DM CLR re-query: Response "Left lobe" is noted. Please update the Adverse event name to reflect your response. Thank you. ' (Site from DM).		16 Feb 2021 08:58:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:29

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review AE and please update to specify the location of Left Sided Lymphadenitis. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'Left lobe' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 20:17:27
User opened query 'Per DM CLR: Please review AE and please update to specify the location of Left Sided Lymphadenitis. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).		25 Oct 2020 00:41:52
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenitis, LLT: Lymphadenitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:46:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:46:28
Data point term sent to Coder	System	16 Oct 2020 15:13:08
User entered 'Left sided lymphadenitis'	Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:12:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE started after the 7-day post vaccination period for collecting solicited events. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE started after the 7-day post vaccination period for collecting solicited events. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' answered with 'reviewed and updated' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 08:54:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 20:12:17
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE started after the 7-day post vaccination period for collecting solicited events. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 18:48:24
User entered 'Yes (Y)'	Nicole Davis (b) (4)	25 Oct 2020 00:39:34
	(b) (4)	16 Oct 2020 15:12:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'No (N)'	(b) (4) Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '01 Oct 2020'	(b) (4) Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48



**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered empty.	(b) (4) Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
User entered empty.	System	16 Oct 2020 15:12:48

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'No (N)'	(b) (4) Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '13 Oct 2020'	(b) (4) Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered empty.	(b) (4)	
	Nicole Davis (b) (4)	16 Oct 2020 15:12:48
	(b) (4)	

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
User entered empty.	System	16 Oct 2020 15:12:48

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'No (N)'	(b) (4) Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48



**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '0'	(b) (4) Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '0'	(b) (4) Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '0'	(b) (4) Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered empty.	(b) (4) Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered empty.	(b) (4) Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered empty.	(b) (4) Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered empty.	(b) (4)	
	Nicole Davis (b) (4)	16 Oct 2020 15:12:48
	(b) (4)	

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '0'	(b) (4) Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48



**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '0'	(b) (4) Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '0'	(b) (4) Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Feb 2021 18:49:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Feb 2021 18:49:15
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 18:49:15
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 15:12:48
User entered empty.	Nicole Davis (b) (4)	16 Oct 2020 15:12:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Feb 2021 18:49:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Feb 2021 18:49:15
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 18:49:15
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 15:12:48
User entered empty.	Nicole Davis (b) (4)	16 Oct 2020 15:12:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:29

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User closed query 'Per CDM: Per CCGs, if the Adverse event started during a time period when study dose was not given, "Not applicable" should be selected for "Action taken with investigational product". Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 02:52:22
Query 'Per CDM: Per CCGs, if the Adverse event started during a time period when study dose was not given, "Not applicable" should be selected for "Action taken with investigational product". Please review and update as appropriate. ' answered with 'Reviewed and updated' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 13:04:40
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 13:03:51
User opened query 'Per CDM: Per CCGs, if the Adverse event started during a time period when study dose was not given, "Not applicable" should be selected for "Action taken with investigational product". Please review and update as appropriate. ' (Site from DM).		05 Mar 2021 12:25:23
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Feb 2021 18:49:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Feb 2021 18:49:15
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 18:49:15
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 15:12:48
User entered empty.	Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:29

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 02:23:46
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 20:27:02
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 20:26:27
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).		19 Mar 2021 20:12:22
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Feb 2021 18:49:15
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 18:49:15
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Oct 2020 15:12:48
User entered '0'	Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:26:27
User entered '0'	Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '0'	(b) (4) Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[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 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered empty.	(b) (4) Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:29

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User closed query 'Per CDM, DM CLR re-query: Please note that there is no procedure recorded on the Concomitant Procedures page and per SAE narrative subject had Eyebrow Lift Surgery. Please update to record the procedure as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 11:40:54
Query 'Per CDM, DM CLR re-query: Please note that there is no procedure recorded on the Concomitant Procedures page and per SAE narrative subject had Eyebrow Lift Surgery. Please update to record the procedure as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 19:22:43
User closed query 'Per DM CLR: SAE Narrative indicates that an unknown antibiotic was used as treatment for this AE. However, there is no corresponding ConMed record that match this information. Please update applicable details as appropriate. Otherwise, clarify.' (Site from DM).		16 Feb 2021 09:05:21
User closed query 'Per DM CLR: SAE Narrative indicates that the subject had Eyebrow Lift Surgery. However, there is no corresponding Concomitant Procedure record to match this information. Please update to record the procedure as appropriate. Otherwise, clarify.' (Site from DM).		16 Feb 2021 09:04:00
User opened query 'Per CDM, DM CLR re-query: Please note that there is no procedure recorded on the Concomitant Procedures page and per SAE narrative subject had Eyebrow Lift Surgery. Please update to record the procedure as appropriate. ' (Site from DM).		16 Feb 2021 09:03:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:29

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative indicates that an unknown antibiotic was used as treatment for this AE. However, there is no corresponding ConMed record that match this information. Please update applicable details as appropriate. Otherwise, clarify.'	(b) (4), (b) (6)	15 Feb 2021 20:18:10
answered with 'reviewed and updated' (Site from DM).		
Query 'Per DM CLR: SAE Narrative indicates that the subject had Eyebrow Lift Surgery. However, there is no corresponding Concomitant Procedure record to match this information. Please update to record the procedure as appropriate. Otherwise, clarify.'		15 Feb 2021 20:18:05
answered with 'reviewed and updated' (Site from DM).		
User opened query 'Per DM CLR: SAE Narrative indicates that an unknown antibiotic was used as treatment for this AE. However, there is no corresponding ConMed record that match this information. Please update applicable details as appropriate. Otherwise, clarify.'		25 Oct 2020 00:41:33
(Site from DM).		
User opened query 'Per DM CLR: SAE Narrative indicates that the subject had Eyebrow Lift Surgery. However, there is no corresponding Concomitant Procedure record to match this information. Please update to record the procedure as appropriate. Otherwise, clarify.'		25 Oct 2020 00:41:23
(Site from DM).		
User entered 'Participant had 2nd injection 17-Sep-2020. Patient reported he had to be treated for an infected saliva gland, due to large swelling of left neck. Patient was placed on unknown PO antibiotic from 03-Oct-2020 thru 13-Oct-2020. Patient also had eyebrow lift surgery between 1st and second injection.'	Nicole Davis (b) (4) (b) (4)	16 Oct 2020 15:12:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
User entered '0'	System	16 Oct 2020 15:12:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26
User entered '1'	System	16 Oct 2020 15:12:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:21:26

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:29**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered	(b) (4)	01 Mar 2021 17:36:11
'USA-US117-2021-mRNA-1273-P301000002'	System	01 Mar 2021 17:36:11
User entered 'New'	(b) (4), (b) (6)	01 Mar 2021 17:36:11



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:56:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms malignant and unspecified, HLT: Thyroid neoplasms malignant, PT: Thyroid cancer, LLT: Thyroid cancer - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 19:29:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 19:29:02
Data point term sent to Coder	System	26 Feb 2021 19:27:51
User entered 'thyroid cancer'	(b) (4), (b) (6)	26 Feb 2021 19:27:38

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:27:38

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:27:38

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:27:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:56:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:49:58
DataPoint Verified.	(b) (4)	21 Apr 2021 17:43:06
	(b) (4), (b) (6)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Apr 2021 14:12:31
User entered '22 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 14:12:31
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Apr 2021 14:12:15
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 14:12:15
Signature has been broken.		21 Apr 2021 14:12:15
User entered 'un Oct 2020' (non-conformant).		21 Apr 2021 14:12:15
DataPoint Verified.		15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
	(b) (4)	
User closed query 'PV Query: Please confirm event start date as biopsy taken on 22 Oct 2020 revealed thyroid cancer.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 16:29:18
Query 'PV Query: Please confirm event start date as biopsy taken on 22 Oct 2020 revealed thyroid cancer. answered with 'Confirmed date' (Site from Safety).		10 Mar 2021 13:15:02
User entered '22 Oct 2020' reason for change: Data Entry Error		10 Mar 2021 13:14:28
User opened query 'PV Query: Please confirm event start date as biopsy taken on 22 Oct 2020 revealed thyroid cancer.' (Site from Safety).		06 Mar 2021 21:40:22
User entered '30 Oct 2020'		26 Feb 2021 19:27:38

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:27:38

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 19:27:38

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	13 Apr 2021 20:36:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 19:27:38



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Generated On: 09 Jun 2021 14:56:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:49:58
DataPoint Verified.	(b) (4)	21 Apr 2021 17:42:52
User closed query 'per source there is no resolved date. please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:42:50
Query 'per source there is no resolved date. please review and reconcile. ' answered with 'updated.		21 Apr 2021 14:12:56
subject just had last blood work and was cancer free' (Site from CRA).		
Signature has been broken.		21 Apr 2021 14:12:15
User entered '14 Apr 2021' reason for change: Data Entry Error		21 Apr 2021 14:12:15
DataPoint Un-verified.		15 Apr 2021 16:41:07
DataPoint Verified.		15 Apr 2021 16:41:05
User opened query 'per source there is no resolved date. please review and reconcile. ' (Site from CRA).		15 Apr 2021 16:41:01
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '26 Jan 2021' reason for change: Data Entry Error	(b) (4)	13 Apr 2021 20:36:42
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 16:29:23
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Still on going' (Site from Safety).		10 Mar 2021 13:20:26
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		06 Mar 2021 21:39:23
User entered empty.		26 Feb 2021 19:27:38

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End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:32:31
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'noted' (Site from Safety).	Avia McClain-Stocker (b) (4)	13 Apr 2021 20:27:56
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 12:45:54
User entered empty.		26 Feb 2021 19:27:38

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 19:27:38

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:27:38

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
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).	(b) (4)	26 Feb 2021 19:33:06
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	26 Feb 2021 19:27:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 19:27:38

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:27:38

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:33:06
User entered '0'		26 Feb 2021 19:27:38

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 19:27:38



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[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:27:38

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:27:38

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:27:38

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:27:38

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:27:38

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:27:38

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:27:38

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:27:38



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:27:38

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	10 Mar 2021 13:23:18
reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered 'None (NONE)'		26 Feb 2021 19:27:38

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:29**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:27:38

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:27:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:56:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User closed query 'PV Query: Please provide date of ultrasound.' (Site from Safety).	(b) (4)	11 Mar 2021 16:29:27
Query 'PV Query: Please provide date of ultrasound.' answered with 'No source found' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 13:22:23
User opened query 'PV Query: Please provide date of ultrasound.' (Site from Safety).		06 Mar 2021 21:39:58
User entered 'I'		26 Feb 2021 19:27:38

US3052220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:56:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:33:13
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	Avia McClain-Stocker (b) (4)	13 Apr 2021 20:36:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	13 Apr 2021 20:36:42
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 12:46:11
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		11 Mar 2021 16:29:30
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Still ongoing' (Site from Safety).		10 Mar 2021 13:22:38
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		06 Mar 2021 21:39:43
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'		26 Feb 2021 19:27:38

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:27:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:56:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:41:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User closed query 'Per CDM CLR Re-query: Per response however radiotherapy is not reflecting in the concomitant procedure page. Kindly review and amend as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 04:52:37
Query 'Per CDM CLR Re-query: Per response however radiotherapy is not reflecting in the concomitant procedure page. Kindly review and amend as appropriate.' answered with 'addedto procedures and in source' (Site from DM).	Avia McClain-Stocker (b) (4)	13 Apr 2021 20:37:02
User opened query 'Per CDM CLR Re-query: Per response however radiotherapy is not reflecting in the concomitant procedure page. Kindly review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 15:45:13
User closed query 'Per DM CLR: Narrative indicates that the subject is also receiving Radiotherapy. However, there is no corresponding Concomitant Procedure record that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM).		02 Apr 2021 15:45:13
Query 'Per DM CLR: Narrative indicates that the subject is also receiving Radiotherapy. However, there is no corresponding Concomitant Procedure record that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).		25 Mar 2021 20:30:41
User opened query 'Per DM CLR: Narrative indicates that the subject is also receiving Radiotherapy. However, there is no corresponding Concomitant Procedure record that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM).		19 Mar 2021 20:13:59
User closed query 'Per DM CLR: Narrative = ULTRASOUND. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		16 Mar 2021 15:23:55



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:56:29

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = RADIOTHERAPY. 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)	16 Mar 2021 15:23:52
User closed query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).		11 Mar 2021 16:29:38
Query 'Per DM CLR: Narrative = RADIOTHERAPY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Reviewed and updated' (Site from DM).		10 Mar 2021 13:24:29
Query 'Per DM CLR: Narrative = ULTRASOUND. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Reviewed and updated' (Site from DM).		10 Mar 2021 13:24:12
Query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'Reviewed and updated' (Site from Safety).		10 Mar 2021 13:23:35
User opened query 'Per DM CLR: Narrative = RADIOTHERAPY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		10 Mar 2021 12:16:35
User opened query 'Per DM CLR: Narrative = ULTRASOUND. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		10 Mar 2021 12:16:30
User opened query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).		06 Mar 2021 21:38:58
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Feb 2021 19:31:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:56:29

[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	26 Feb 2021 19:31:15
User entered 'PARTICIPANT HAD 2ND INJECTION 17-SEP-2020. PATIENT REPORTED HE HAD TO BE TREATED FOR AN INFECTED SALIVA GLAND, DUE TO LARGE SWELLING OF LEFT NECK. PATIENT WAS PLACED ON UNKNOWN PO ANTIBIOTIC FROM 03-OCT-2020 THRU 13-OCT-2020. through an ultrasound to check the gland nodules were discovered on the thyroid. biopsy done with a diagnosis of thyroid cancer. the thyroid was removed and subject put on Synthroid as well as currently receiving radiotherapy .' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 19:31:15
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Feb 2021 19:27:38
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 19:27:38

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 19:27:38

**US3052220**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 19:27:38

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:56:29

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:41
DataPoint Verified.		05 Apr 2021 16:25:06
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:14:41

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE HYDROCHLORIDE, PRODUCTSYNONYM: EFFEXOR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Aug 2020 06:38:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:38:18
Data point term sent to Coder	System	19 Aug 2020 19:16:08
User entered 'Effexor'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:15:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:15:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Unknown'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:15:53



US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '75'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:15:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'mg (mg)'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:15:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:29

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:15:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'once daily (QD)'	amy sheets (b) (4)	19 Aug 2020 19:15:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:15:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:15:53

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:15:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:15:53



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:15:53

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Yes (Y)'	amy sheets (b) (4)	19 Aug 2020 19:15:53

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:15:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 11:21:31
Query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' answered with 'reviewed source documents and updated. ' (Site from DM).	Avia McClain-Stocker (b) (4)	14 Oct 2020 15:32:49
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	14 Oct 2020 15:32:28
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 04:27:27
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:15:53

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:15:53

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:15:53

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:15:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM, PRODUCTSYNONYM: CLONAZEPAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 00:19:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 00:19:22
Data point term sent to Coder	System	19 Aug 2020 19:17:10
User entered 'Clonazepan'	amy sheets (b) (4)	19 Aug 2020 19:16:38



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Yes (Y)'	amy sheets (b) (4)	19 Aug 2020 19:16:38

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Unknown'	amy sheets (b) (4)	19 Aug 2020 19:16:38

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:16:38

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'mg (mg)'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:16:38

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:29

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:16:38

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'once daily (QD)'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:16:38

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:16:38

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:16:38



US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:16:38

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:16:38

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:16:38

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:16:38

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:16:38

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 11:21:18
Query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' answered with 'reviewed source documents and updated. ' (Site from DM).	Avia McClain-Stocker (b) (4)	14 Oct 2020 15:32:58
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	14 Oct 2020 15:32:54
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 04:11:07
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:16:38

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:16:38

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:16:38



**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:16:38

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 06:43:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 06:43:11
Data point term sent to Coder	System	19 Aug 2020 19:18:13
User entered 'Omeprazole'	amy sheets (b) (4)	19 Aug 2020 19:17:48

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Yes (Y)'	amy sheets (b) (4)	19 Aug 2020 19:17:48

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:56:29**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Unknown'	amy sheets (b) (4)	19 Aug 2020 19:17:48

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '20'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:17:48

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'mg (mg)'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:17:48

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:29

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:17:48

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'once daily (QD)'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:17:48



US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:17:48

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:17:48

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:17:48

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	amy sheets (b) (4)	19 Aug 2020 19:17:48

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'I'	amy sheets (b) (4)	19 Aug 2020 19:17:48

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Yes (Y)'	amy sheets (b) (4)	19 Aug 2020 19:17:48

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:17:48

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 11:21:48
Query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' answered with 'reviewed source documents and updated. ' (Site from DM).	Avia McClain-Stocker (b) (4)	14 Oct 2020 15:33:11
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	14 Oct 2020 15:33:07
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 04:28:04
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:17:48



**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:56:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:17:48

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:56:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:17:48

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:56:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:17:48

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 21:49:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 21:49:15
Data point term sent to Coder	System	19 Aug 2020 19:19:18
User entered 'Alprazolam'	amy sheets (b) (4)	19 Aug 2020 19:18:57

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:18:57

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:29**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'unknown'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:18:57

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:18:57

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'mg (mg)'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:18:57



US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:29

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:18:57

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'once daily (QD)'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:18:57

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:18:57

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:18:57

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:18:57

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:18:57

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:18:57

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:18:57



US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:18:57

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 11:20:40
Query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' answered with 'reviewed source documents and updated. ' (Site from DM).	Avia McClain-Stocker (b) (4)	14 Oct 2020 15:33:24
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	14 Oct 2020 15:33:21
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 04:10:23
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:18:57

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:18:57

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:18:57

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:18:57

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: TEMAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 01:13:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 01:13:12
Data point term sent to Coder	System	19 Aug 2020 19:20:27
User entered 'Temazepam'	amy sheets (b) (4)	19 Aug 2020 19:19:51

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Yes (Y)'	amy sheets (b) (4)	19 Aug 2020 19:19:51

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:56:29**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Unknown'	amy sheets (b) (4)	19 Aug 2020 19:19:51



US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '30' reason for change: Data Entry Error	(b) (4)	
	amy sheets (b) (4)	19 Aug 2020 19:20:15
User entered '30o'	(b) (4)	
	amy sheets (b) (4)	19 Aug 2020 19:19:51
	(b) (4)	

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'mg (mg)'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:19:51

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:29

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:19:51

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'once daily (QD)'	amy sheets (b) (4)	19 Aug 2020 19:19:51

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:19:51

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Oral (ORAL)'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:19:51

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:29

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:19:51

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:19:51



US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'I'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:19:51

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:19:51

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	19 Aug 2020 19:19:51

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 11:22:00
Query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' answered with 'reviewed source documents and updated. ' (Site from DM).	Avia McClain-Stocker (b) (4)	14 Oct 2020 15:33:34
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	14 Oct 2020 15:33:30
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes. However, the Indication is not included as one of the solicited AE per protocol. Update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 04:28:29
User entered 'Yes (Y)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:19:51

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:56:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:19:51

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:56:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:19:51

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:56:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:19:51

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
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)	12 Mar 2021 11:45:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 11:45:51
Data point term sent to Coder	System	10 Mar 2021 13:50:04
Coding entries removed.	(b) (4), (b) (6)	10 Mar 2021 13:50:03
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)	16 Feb 2021 10:45:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 10:45:55
Data point term sent to Coder	System	15 Feb 2021 20:31:40
Data point term sent to Coder	System	15 Feb 2021 20:30:39
User entered 'Flu Shot'	(b) (4), (b) (6)	15 Feb 2021 20:30:33



US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User closed query 'Per DM CLR: Indication reflect prophylaxis, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4)	12 Mar 2021 02:52:49
Query 'Per DM CLR: Indication reflect prophylaxis, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' answered with 'Reviewed and updated' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 13:39:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 13:39:37
User opened query 'Per DM CLR: Indication reflect prophylaxis, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Mar 2021 10:40:38
User entered 'No (N)'	(b) (4), (b) (6)	15 Feb 2021 20:30:33

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Feb 2021 20:31:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Feb 2021 20:31:04
User entered 'seasonal vaccine' reason for change:	(b) (4), (b) (6)	15 Feb 2021 20:31:04
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Feb 2021 20:30:33
User entered empty.	(b) (4), (b) (6)	15 Feb 2021 20:30:33

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'l'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:30:33

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:30:33

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Injection'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:30:33

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:30:33

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:30:33

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4)	(b) (4), (b) (6)
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'Reviewed and corrected' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 02:53:03
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 13:52:08
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 13:50:03
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	07 Mar 2021 10:40:56
	(b) (4), (b) (6)	15 Feb 2021 20:30:33



**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	15 Feb 2021 20:30:33
	(b) (4), (b) (6)	

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:30:33

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:30:33

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:30:33

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:30:33

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:30:33

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
User entered empty.	System	15 Feb 2021 20:30:33

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
User entered empty.	System	15 Feb 2021 20:30:33



**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:24
User entered empty.	System	15 Feb 2021 20:30:33

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:20
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:04:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Apr 2021 07:15:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Apr 2021 07:15:49
Data point term sent to Coder	System	14 Apr 2021 18:43:24
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 18:42:27
Coding entries removed.		14 Apr 2021 18:42:27
Signature has been broken.		14 Apr 2021 18:42:27
User entered 'augmentin' reason for change: Data Entry Error		14 Apr 2021 18:42:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, PRODUCT: ANTIBIOTICS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 15:24:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 15:24:53
Data point term sent to Coder	System	14 Apr 2021 15:23:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, PRODUCT: ANTIBIOTICS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 15:23:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Apr 2021 15:23:13

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:29

Name of Medication

Audit	User	Time (GMT)
Query 'CDM Coding : Please provide the specific trade name for the reported medication ANTIBIOTICS and update the response in the drug name field along with active ingredients. Thank you. ' canceled (Site from System).	Coder Import (b) (4)	14 Apr 2021 15:23:03
User opened query 'CDM Coding : Please provide the specific trade name for the reported medication ANTIBIOTICS and update the response in the drug name field along with active ingredients. Thank you. ' (Site from System).	Coder Import (b) (4)	14 Apr 2021 08:42:42
Data point term sent to Coder	System	13 Apr 2021 20:39:48
Coding entries removed.	Avia McClain-Stocker	13 Apr 2021 20:39:23
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User closed query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 10:36:50
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
Query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate.' answered with 'Pt did not provide name of antibiotic' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 13:56:34
User opened query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Mar 2021 10:43:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, PRODUCT: ANTIBIOTICS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Feb 2021 23:46:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Feb 2021 23:46:45
Data point term sent to Coder	System	15 Feb 2021 20:37:53

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:29**

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Antibiotics'	(b) (4), (b) (6)	15 Feb 2021 20:36:49

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:20
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	(b) (4)	15 Mar 2021 17:35:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:36:49

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:20
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:04:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User closed query 'Per CDM, DM CLR re-query: Response noted; however the Other action taken field does not indicate Concomitant medication on the corresponding AE. Review and update the other action taken field as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:07:22
Query 'Per CDM, DM CLR re-query: Response noted; however the Other action taken field does not indicate Concomitant medication on the corresponding AE. Review and update the other action taken field as appropriate. ' answered with 'updated' (Site from DM).	Avia McClain-Stocker (b) (4)	13 Apr 2021 20:39:35
DataPoint Un-verified.	Avia McClain-Stocker (b) (4)	13 Apr 2021 20:39:23
Signature has been broken.	Avia McClain-Stocker (b) (4)	13 Apr 2021 20:39:23
User entered 'left-sided lymphadenitis of the salivary gland' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	13 Apr 2021 20:39:23
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User opened query 'Per CDM, DM CLR re-query: Response noted; however the Other action taken field does not indicate Concomitant medication on the corresponding AE. Review and update the other action taken field as appropriate. ' (Site from DM).		16 Mar 2021 15:07:19
User closed query 'Per DM CLR: The corresponding recorded AE does not show 'ConMed Administered' for Action Taken. Please update Action Taken for AE as appropriate.' (Site from DM).		16 Mar 2021 15:07:19
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
Query 'Per DM CLR: The corresponding recorded AE does not show 'ConMed Administered' for Action Taken. Please update Action Taken for AE as appropriate.' answered with 'Reviewed and updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 14:10:29

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:29

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: The corresponding recorded AE does not show 'ConMed Administered' for Action Taken. Please update Action Taken for AE as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Mar 2021 10:43:33
User entered 'Salivary gland infection'		15 Feb 2021 20:36:49

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:20
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:04:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:42:27
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 18:42:27
User entered '875' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 18:42:27
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'UN'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:36:49



US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:20
DataPoint Verified.		22 Apr 2021 15:04:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:42:27
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 18:42:27
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 18:42:27
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:36:49

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:20
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:04:05
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:42:27
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 18:42:27
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 18:42:27
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:36:49

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:20
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:36:49

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:20
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:36:49

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:20
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:36:49

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:20
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:36:49

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:20
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '3 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:36:49

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:20
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:36:49



**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:20
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:36:49

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:29**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:20
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:36:49

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:20
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:36:49

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:20
User entered '3'	System	15 Feb 2021 20:36:49

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:20
User entered '1'	System	15 Feb 2021 20:36:49

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:29:20
User entered '804 (804)'	System	15 Feb 2021 20:36:49

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 19:40:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Feb 2021 19:40:53
Data point term sent to Coder	System	26 Feb 2021 19:40:18
User entered 'synthroid'	(b) (4), (b) (6)	26 Feb 2021 19:39:21

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:39:21



US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 02:57:28
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Medical condition still ongoing' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 14:08:16
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).		09 Mar 2021 07:27:40
User entered 'Thyroid Cancer'		26 Feb 2021 19:39:21

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:49:58
DataPoint Verified.	(b) (4)	21 Apr 2021 17:43:47
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 14:09:07
Signature has been broken.		21 Apr 2021 14:09:07
User entered '168' reason for change: Data Entry Error		21 Apr 2021 14:09:07
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4)	12 Mar 2021 02:57:36
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Per source pt stated the dose is 160' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 14:00:35
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).		09 Mar 2021 07:27:48
User entered '160'		26 Feb 2021 19:39:21

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:49:58
DataPoint Verified.	(b) (4)	21 Apr 2021 17:43:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 14:09:07
Signature has been broken.		21 Apr 2021 14:09:07
User entered 'Other (OTHER)' reason for change:		21 Apr 2021 14:09:07
Data Entry Error		
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'ug (ug)'	(b) (4)	26 Feb 2021 19:39:21
	(b) (4), (b) (6)	

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:49:58
DataPoint Verified.	(b) (4)	21 Apr 2021 17:43:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 14:09:07
Signature has been broken.		21 Apr 2021 14:09:07
User entered 'mcg' reason for change: Data Entry Error		21 Apr 2021 14:09:07
DataPoint Verified.		05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4)	26 Feb 2021 19:39:21
	(b) (4), (b) (6)	

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:39:21

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:39:21

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:29**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:39:21

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:39:21



**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'UN Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:39:21

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:39:21

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:29**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:39:21

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:39:21

US3052220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:28:38
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:39:21

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 19:39:21

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Feb 2021 19:39:21

**US3052220**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Feb 2021 19:39:21



US3052220

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:56:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:41
User closed query 'Please provide source for all procedures.' (Site from CRA).		15 Apr 2021 16:34:45
User closed query 'Per CDM, DM CLR re-queries on AE #2: SAE Narrative indicates ULTRASOUND and RADIOTHERAPY; however, these are not recorded on the Con Proc page. lease review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).		15 Apr 2021 11:25:45
Query 'Please provide source for all procedures.' answered with 'updated in source' (Site from CRA).	Avia McClain-Stocker (b) (4)	13 Apr 2021 20:41:16
Query 'Per CDM, DM CLR re-queries on AE #2: SAE Narrative indicates ULTRASOUND and RADIOTHERAPY; however, these are not recorded on the Con Proc page. lease review and ensure that these are captured in the appropriate eCRF. ' answered with 'updated in both' (Site from DM).	Avia McClain-Stocker (b) (4)	13 Apr 2021 20:41:09
User opened query 'Please provide source for all procedures.' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 16:30:59
User opened query 'Per CDM, DM CLR re-queries on AE #2: SAE Narrative indicates ULTRASOUND and RADIOTHERAPY; however, these are not recorded on the Con Proc page. lease review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).		16 Mar 2021 15:23:40
User signature succeeded.	Judith Borger (b) (4) (b) (4)	15 Mar 2021 17:35:46
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:32:27
User closed query 'Per source, subject had an eyebrow lift surgery between first and second visit. Please review source and create a concomitant procedure entry if appropriate.' (Site from CRA).		04 Mar 2021 20:32:25
User entered 'Yes (Y)' reason for change: Data Entry Error		26 Feb 2021 19:28:11
Query 'Per source, subject had an eyebrow lift surgery between first and second visit. Please review source and create a concomitant procedure entry if appropriate.' answered with 'subject had a cosmetic brow lift' (Site from CRA).		26 Feb 2021 18:57:37

US3052220

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:56:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 18:57:16
User entered 'Yes (Y)' reason for change: Data Entry Error		26 Feb 2021 18:53:38
User opened query 'Per source, subject had an eyebrow lift surgery between first and second visit. Please review source and create a concomitant procedure entry if appropriate.' (Site from CRA).		03 Dec 2020 19:43:21
User entered 'No (N)'	amy sheets (b) (4) (b) (4)	19 Aug 2020 19:20:33

US3052220

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:56:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:11
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:49:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:45:36
Signature has been broken.	Avia McClain-Stocker	13 Apr 2021 20:40:05
User signature succeeded.	(b) (4) Judith Borger (b) (4)	15 Mar 2021 17:35:46
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	26 Feb 2021 19:14:53
User entered '1 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 19:14:53
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Feb 2021 19:13:56
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Feb 2021 19:13:56
User entered 'nd Sep 2020' (non-conformant).	(b) (4), (b) (6)	26 Feb 2021 19:13:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Feb 2021 19:13:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Feb 2021 19:13:49
User entered 'un Sep 2020' (non-conformant).	(b) (4), (b) (6)	26 Feb 2021 19:13:49
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Feb 2021 19:13:41
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Feb 2021 19:13:41
User entered '00 Sep 2020' (non-conformant).	(b) (4), (b) (6)	26 Feb 2021 19:13:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Feb 2021 19:13:34
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 19:13:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Feb 2021 19:13:34
User entered 'Sep 2020' (non-conformant).	(b) (4), (b) (6)	26 Feb 2021 19:13:34
DataPoint activated with code reason code Data required.		26 Feb 2021 19:11:54

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:56:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	26 Feb 2021 18:57:04
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 18:56:51
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Feb 2021 18:56:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 18:56:51
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Feb 2021 18:55:17
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Feb 2021 18:55:17
User entered 'un Sep 2020' (non-conformant).	(b) (4), (b) (6)	26 Feb 2021 18:55:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Feb 2021 18:54:58
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Feb 2021 18:54:58
User entered ' Sep 2020' (non-conformant).	(b) (4), (b) (6)	26 Feb 2021 18:54:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Feb 2021 18:54:41
User entered 'un Sep 2020' (non-conformant).	(b) (4), (b) (6)	26 Feb 2021 18:54:41

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:56:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:11
DataPoint Verified.		22 Apr 2021 15:45:36
User closed query 'Source not provided.' (Site from CRA).		22 Apr 2021 15:37:59
Query 'Source not provided.' answered with 'progress note dated 10/15/20 in the chart' (Site from CRA).		20 Apr 2021 19:14:23
User opened query 'Source not provided.' (Site from CRA).		15 Apr 2021 16:38:32
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	26 Feb 2021 19:13:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Feb 2021 19:13:34
User entered 'brow lift' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 19:13:34
DataPoint activated with code reason code Data required.		26 Feb 2021 19:11:54
DataPoint inactivated with code reason code Data not required.		26 Feb 2021 18:57:04
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 18:56:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 18:56:51
User entered 'brow lift'		26 Feb 2021 18:54:41

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:56:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:11
DataPoint Verified.	(b) (4)	22 Apr 2021 15:45:36
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 19:13:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Feb 2021 19:13:34
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 19:13:34
DataPoint activated with code reason code Data required.	(b) (4)	26 Feb 2021 19:11:54
DataPoint inactivated with code reason code Data no required.	(b) (4)	26 Feb 2021 18:57:04
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Feb 2021 18:56:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 18:56:51
User entered 'Other (OTHER)'	(b) (4)	26 Feb 2021 18:54:41

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:56:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:11
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:45:36
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'cosmetic' reason for change: Data Entry Error	(b) (4)	(b) (4), (b) (6)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	26 Feb 2021 19:13:34
DataPoint inactivated with code reason code Data no required.	(b) (4), (b) (6)	26 Feb 2021 19:11:54
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 18:57:04
User entered 'cosmetic'	(b) (4), (b) (6)	26 Feb 2021 18:56:51
	(b) (4), (b) (6)	26 Feb 2021 18:54:41

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:56:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:13
DataPoint Verified.		22 Apr 2021 15:45:36
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:20:57



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:56:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:13
DataPoint Verified.		22 Apr 2021 15:45:36
User closed query 'Source not provided.' (Site from CRA).		22 Apr 2021 15:41:00
Query 'Source not provided.' answered with 'progress note dated 10/15/2020 in the chart describing how a CT scan revealed the nodules on his thyroid' (Site from CRA).		20 Apr 2021 19:15:59
User opened query 'Source not provided.' (Site from CRA).		15 Apr 2021 16:38:27
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'biopsy of nodule in thyroid'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:20:57

**US3052220**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:13
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 15:45:36
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:20:57

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:56:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:13
DataPoint Verified.		22 Apr 2021 15:45:36
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:20:57

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:56:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:17
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:49:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:45:36
User closed query 'Per source, date was Un Jan 2021.' (Site from CRA).		22 Apr 2021 15:42:55
User entered '04 Jan 2021' reason for change: Data Entry Error		21 Apr 2021 14:10:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Apr 2021 19:17:32
User entered '26 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 19:17:32
Query 'Per source, date was Un Jan 2021.' answered with 'updated.' (Site from CRA).		20 Apr 2021 15:40:09
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Apr 2021 15:13:59
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 15:13:59
User entered 'un Jan 2021' (non-conformant).		20 Apr 2021 15:13:59
User opened query 'Per source, date was Un Jan 2021.' (Site from CRA).		15 Apr 2021 16:38:10
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered '4 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:24:23
User entered '12 Feb 2021'		26 Feb 2021 19:22:22

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:56:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:17
DataPoint Verified.		22 Apr 2021 15:45:36
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Thyroidectomy'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:22:22

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:56:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:17
DataPoint Verified.		22 Apr 2021 15:45:36
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:22:22

US3052220

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:56:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:17
DataPoint Verified.		22 Apr 2021 15:45:36
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:35:46
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:22:22

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:56:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Thank you for adding the procedure in response to DM CLR queries on AE#2 . Please note that the narrative on AE#2 indicates that "THE THYROID WAS REMOVED AND SUBJECT PUT ON SYNTHROID AS WELL AS CURRENTLY RECEIVING RADIOTHERAPY"; however the date of Radiotherapy recorded here is prior to the date of Thyroidectomy (Con Proc #3). Please review and verify the date of Radiotherapy. If multiple procedures of Radiotherapy are performed, then please ensure these are also recorded. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 09:07:35
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:49:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:45:36
Query 'Per CDM: Thank you for adding the procedure in response to DM CLR queries on AE#2 . Please note that the narrative on AE#2 indicates that "THE THYROID WAS REMOVED AND SUBJECT PUT ON SYNTHROID AS WELL AS CURRENTLY RECEIVING RADIOTHERAPY"; however the date of Radiotherapy recorded here is prior to the date of Thyroidectomy (Con Proc #3). Please review and verify the date of Radiotherapy. If multiple procedures of Radiotherapy are performed, then please ensure these are also recorded. Thank you. ' answered with 'updated' (Site from DM).		21 Apr 2021 14:09:39
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 14:09:30





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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:56:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:49:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:45:36
User entered 'Radiotherapy'	Avia McClain-Stocker	13 Apr 2021 20:33:39
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:56:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:49:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:45:36
User entered 'Adverse Event (AE)'	Avia McClain-Stocker	13 Apr 2021 20:33:39
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:56:29

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:49:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 15:45:36
User entered empty.	Avia McClain-Stocker	13 Apr 2021 20:33:39
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:56:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:19
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:49:58
DataPoint Verified.	(b) (4)	22 Apr 2021 15:45:36
User entered '22 Oct 2020'	Avia McClain-Stocker	13 Apr 2021 20:33:58
	(b) (4)	

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**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 09 Jun 2021 14:56:29**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:19
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:49:58
DataPoint Verified.	(b) (4)	22 Apr 2021 15:45:36
User entered 'ultrasound'	Avia McClain-Stocker	13 Apr 2021 20:33:58
	(b) (4)	

**US3052220**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 09 Jun 2021 14:56:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:19
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:49:58
DataPoint Verified.	(b) (4)	22 Apr 2021 15:45:36
User entered 'Adverse Event (AE)'	Avia McClain-Stocker	13 Apr 2021 20:33:58
	(b) (4)	

US3052220

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:56:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:19
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:49:58
DataPoint Verified.	(b) (4)	22 Apr 2021 15:45:36
User entered empty.	Avia McClain-Stocker	13 Apr 2021 20:33:58
	(b) (4)	



**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'USA-US117-2021-MRNA-1273-P301000002'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'Yes (Y)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'Yes (Y)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11



US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
Un-reviewed for Safety.	(b) (4)	14 Apr 2021 15:34:26
DataPoint Un-verified.	System	14 Apr 2021 15:34:26
Signature has been broken.	System	14 Apr 2021 15:34:26
User entered 'Yaa'	System	14 Apr 2021 15:34:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4)	11 Mar 2021 16:31:42
User entered 'Judith'	(b) (4), (b) (6)	01 Mar 2021 17:36:11
	System	

US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
Un-reviewed for Safety.	(b) (4)	14 Apr 2021 15:34:26
DataPoint Un-verified.	System	14 Apr 2021 15:34:26
Signature has been broken.	System	14 Apr 2021 15:34:26
User entered 'Oppong'	System	14 Apr 2021 15:34:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4)	11 Mar 2021 16:31:42
User entered 'Borger'	(b) (4), (b) (6)	01 Mar 2021 17:36:11
	System	

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '1565 Purdue Drive'	(b) (4) System	14 Apr 2021 15:34:26

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'Fayetteville'	(b) (4) System	14 Apr 2021 15:34:26

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'NC'	(b) (4) System	14 Apr 2021 15:34:26

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '28314'	(b) (4) System	14 Apr 2021 15:34:26

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'US'	System	01 Mar 2021 17:36:24

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 15:09:34
User entered '3'	System	14 Apr 2021 15:34:26
User entered '2'	System	11 Mar 2021 16:31:39
User entered '1'	System	01 Mar 2021 17:36:24



US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'USA-US117-2021-MRNA-1273-P301000002'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'Yes (Y)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'Yes (Y)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11



US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
Un-reviewed for Safety.	(b) (4)	14 Apr 2021 15:34:26
DataPoint Un-verified.	System	14 Apr 2021 15:34:26
Signature has been broken.	System	14 Apr 2021 15:34:26
User entered 'Yaa'	System	14 Apr 2021 15:34:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4)	11 Mar 2021 16:31:42
User entered 'Judith'	(b) (4), (b) (6)	01 Mar 2021 17:36:11
	System	

US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
Un-reviewed for Safety.	(b) (4)	14 Apr 2021 15:34:26
DataPoint Un-verified.	System	14 Apr 2021 15:34:26
Signature has been broken.	System	14 Apr 2021 15:34:26
User entered 'Oppong'	System	14 Apr 2021 15:34:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4)	11 Mar 2021 16:31:42
User entered 'Borger'	(b) (4), (b) (6)	01 Mar 2021 17:36:11
	System	

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '1565 Purdue Drive'	(b) (4) System	14 Apr 2021 15:34:26

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'Fayetteville'	(b) (4) System	14 Apr 2021 15:34:26

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'NC'	(b) (4) System	14 Apr 2021 15:34:26

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '28314'	(b) (4) System	14 Apr 2021 15:34:26

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'US'	System	01 Mar 2021 17:36:24

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 15:09:34
User entered '3'	System	14 Apr 2021 15:34:26
User entered '2'	System	11 Mar 2021 16:31:39
User entered '1'	System	01 Mar 2021 17:36:24



**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 14:56:29**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '01/Mar/2021 12:36'	(b) (4) System	01 Mar 2021 17:36:24

US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:56:29

**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)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'I'		01 Mar 2021 17:36:24

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'USA-US117-2021-MRNA-1273-P301000002'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'Yes (Y)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'Yes (Y)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11



**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
Un-reviewed for Safety.	(b) (4)	14 Apr 2021 15:34:26
DataPoint Un-verified.	System	14 Apr 2021 15:34:26
Signature has been broken.	System	14 Apr 2021 15:34:26
User entered 'Yaa'	System	14 Apr 2021 15:34:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4)	11 Mar 2021 16:31:42
User entered 'Judith'	(b) (4), (b) (6)	01 Mar 2021 17:36:11
	System	

US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
Un-reviewed for Safety.	(b) (4)	14 Apr 2021 15:34:26
DataPoint Un-verified.	System	14 Apr 2021 15:34:26
Signature has been broken.	System	14 Apr 2021 15:34:26
User entered 'Oppong'	System	14 Apr 2021 15:34:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4)	11 Mar 2021 16:31:42
User entered 'Borger'	(b) (4), (b) (6)	01 Mar 2021 17:36:11
	System	

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '1565 Purdue Drive'	(b) (4) System	14 Apr 2021 15:34:26

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'Fayetteville'	(b) (4) System	14 Apr 2021 15:34:26

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'NC'	(b) (4) System	14 Apr 2021 15:34:26

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '28314'	(b) (4) System	14 Apr 2021 15:34:26



**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'US'	System	01 Mar 2021 17:36:24

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 15:09:34
User entered '3'	System	14 Apr 2021 15:34:26
User entered '2'	System	11 Mar 2021 16:31:39
User entered '1'	System	01 Mar 2021 17:36:24

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 14:56:29**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
User entered '11/Mar/2021 11:31'	(b) (4) System	11 Mar 2021 16:31:39

US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:56:29

**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)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'I'		11 Mar 2021 16:31:39

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'USA-US117-2021-MRNA-1273-P301000002'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'Yes (Y)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'Yes (Y)'	System	01 Mar 2021 17:36:11



**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
Un-reviewed for Safety.	(b) (4)	14 Apr 2021 15:34:26
DataPoint Un-verified.	System	14 Apr 2021 15:34:26
Signature has been broken.	System	14 Apr 2021 15:34:26
User entered 'Yaa'	System	14 Apr 2021 15:34:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4)	11 Mar 2021 16:31:42
User entered 'Judith'	(b) (4), (b) (6)	01 Mar 2021 17:36:11
	System	

US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
Un-reviewed for Safety.	(b) (4)	14 Apr 2021 15:34:26
DataPoint Un-verified.	System	14 Apr 2021 15:34:26
Signature has been broken.	System	14 Apr 2021 15:34:26
User entered 'Oppong'	System	14 Apr 2021 15:34:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4)	11 Mar 2021 16:31:42
User entered 'Borger'	(b) (4), (b) (6)	01 Mar 2021 17:36:11
	System	

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '1565 Purdue Drive'	(b) (4) System	14 Apr 2021 15:34:26

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'Fayetteville'	(b) (4) System	14 Apr 2021 15:34:26



**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'NC'	(b) (4) System	14 Apr 2021 15:34:26

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '28314'	(b) (4) System	14 Apr 2021 15:34:26

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'US'	System	01 Mar 2021 17:36:24

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 15:09:34
User entered '3'	System	14 Apr 2021 15:34:26
User entered '2'	System	11 Mar 2021 16:31:39
User entered '1'	System	01 Mar 2021 17:36:24

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 14:56:29**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '14/Apr/2021 08:34'	(b) (4) System	14 Apr 2021 15:34:26

US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:56:29

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:34:26

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'USA-US117-2021-MRNA-1273-P301000002'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'Yes (Y)'	System	01 Mar 2021 17:36:11



**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'Yes (Y)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'No (N)'	System	01 Mar 2021 17:36:11

US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
Un-reviewed for Safety.	(b) (4)	14 Apr 2021 15:34:26
DataPoint Un-verified.	System	14 Apr 2021 15:34:26
Signature has been broken.	System	14 Apr 2021 15:34:26
User entered 'Yaa'	System	14 Apr 2021 15:34:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4)	11 Mar 2021 16:31:42
User entered 'Judith'	(b) (4), (b) (6)	01 Mar 2021 17:36:11
	System	

US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
Un-reviewed for Safety.	(b) (4)	14 Apr 2021 15:34:26
DataPoint Un-verified.	System	14 Apr 2021 15:34:26
Signature has been broken.	System	14 Apr 2021 15:34:26
User entered 'Oppong'	System	14 Apr 2021 15:34:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4)	11 Mar 2021 16:31:42
User entered 'Borger'	(b) (4), (b) (6)	01 Mar 2021 17:36:11
	System	



**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '1565 Purdue Drive'	(b) (4) System	14 Apr 2021 15:34:26

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'Fayetteville'	(b) (4) System	14 Apr 2021 15:34:26

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered 'NC'	(b) (4) System	14 Apr 2021 15:34:26

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:49
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:28:23
User entered '28314'	(b) (4) System	14 Apr 2021 15:34:26

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:34:23
User signature succeeded.	Judith Borger (b) (4)	15 Mar 2021 17:36:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 16:31:42
User entered 'US'	System	01 Mar 2021 17:36:24

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:29**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 15:09:34
User entered '3'	System	14 Apr 2021 15:34:26
User entered '2'	System	11 Mar 2021 16:31:39
User entered '1'	System	01 Mar 2021 17:36:24

**US3052220**

**Folder: SAE USA-US117-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 14:56:29**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:21
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:49:58
User entered '22/Apr/2021 08:09'	(b) (4) System	22 Apr 2021 15:09:34

US3052220

Folder: SAE USA-US117-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:56:29

**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)	26 Apr 2021 16:06:21
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:49:58
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:09:34