

US3022246 (Prod: Meridian Clinical Research-Savannah)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:50:46

All time stamps listed in this document are displayed in GMT

US3022246

Form: Participant Creation

Data signed: (b) (4) 24 Feb 2021 00:25:42

Generated On: 09 Jun 2021 14:50:46

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Participant ID

US3022246

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

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US3022246

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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) 24 Feb 2021 00:25:45

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Date of Birth (MMM yyyy)	(b) (6) 1958
Age	62
Age Units	YEARS
Age (Derived)	62
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) 24 Feb 2021 00:25:45

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	21 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) 24 Feb 2021 00:25:45

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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) 24 Feb 2021 00:25:45

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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) 24 Feb 2021 00:25:45

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Condition	HYPERLIPIDEMIA
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 (2)

Data signed: (b) (4) 24 Feb 2021 00:25:45

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Condition	LEFT HIP ARTHRITIS
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: Vital Signs

Data signed: (b) (4) 24 Feb 2021 00:25:45

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	8:24 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 8:24
Height (xxx.x)	169 cm
Weight (xxx.x)	98.3 kg
BMI (xxx.x)	34.41756 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:25:45

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 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) 24 Feb 2021 00:25:45

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### Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

Specify

NETWORK COMPUTER  
TECHNICIAN - EXPOSED TO  
MANY CLIENTS IN THE FIELD

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

**No Risk Identified** False

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 24 Feb 2021 00:25:45

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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>	True
<b>Specify</b>	LIVES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:25:45

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Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 106834

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) 24 Feb 2021 00:25:45

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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) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

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)	21 AUG 2020
Time of assessment (00:00-23:59)	08:24 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 08:24
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 09:50
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

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) 21 AUG 2020

What was the treatment time? (00:00-23:59) 09:19 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 09:19

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) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 AUG 2020

Collection time (00:00-23:59)

08:30 (24 HR)

Collection date and time (derived)

21 AUG 2020 08:30

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:27	21 AUG 2020 08:27
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

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 14:50:46

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 09:51

PC Open Date & Time

21 AUG 2020 09:39

PC Close Date & Time

21 AUG 2020 12:09

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	21 AUG 2020 18:52
PC Open Date & Time	21 AUG 2020 13:04
PC Close Date & Time	22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**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

97.6 °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

22 AUG 2020 21:01

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 18:52

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:46

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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

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

24 AUG 2020 18:13

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:46

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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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 12:42

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:46

**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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 13:32

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**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

98.5 °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

27 AUG 2020 12:17

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59



US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 09:51

PC Open Date & Time

21 AUG 2020 09:39

PC Close Date & Time

21 AUG 2020 12:09

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**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

21 AUG 2020 18:53

PC Open Date & Time

21 AUG 2020 13:04

PC Close Date & Time

22 AUG 2020 11:59

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**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

22 AUG 2020 21:02

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:46

**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

23 AUG 2020 18:52

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**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

24 AUG 2020 18:13

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**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

25 AUG 2020 12:42

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:46

**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

26 AUG 2020 13:33

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**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

27 AUG 2020 12:17

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59



US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**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 ☐

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 09:52
PC Open Date & Time	21 AUG 2020 09:39
PC Close Date & Time	21 AUG 2020 12:09

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**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 ☐

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 18:53
PC Open Date & Time	21 AUG 2020 13:04
PC Close Date & Time	22 AUG 2020 11:59

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**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 ☒

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:46

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 21:02
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:46

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

46 of 1796

EAB) (1725)

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:46

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 18:53
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59



US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

48 of 1796

EAB) (1725)

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 18:14
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

**DAY 5**

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

50 of 1796

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:46

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 12:42
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:46

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 1796

EAB) (1725)

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:46

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 13:33
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**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 ☒

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:46

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 12:18
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59



US3022246

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3022246

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022246

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022246

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022246

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3022246

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022246

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

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)	24 SEP 2020
Time of assessment (00:00-23:59)	08:35 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 08:35
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG



US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

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)	24 SEP 2020
Time of assessment (00:00-23:59)	10:18 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 10:18
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	70 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)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3022246

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3022246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 09:46 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 09:46

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

US3022246

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 SEP 2020

Collection time (00:00-23:59)

08:55 (24 HR)

Collection date and time (derived)

24 SEP 2020 08:55

US3022246

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:47	24 SEP 2020 08:47
Nasopharyngeal Swab 2	No		

US3022246

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**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

24 SEP 2020 10:20

PC Open Date & Time

24 SEP 2020 10:06

PC Close Date & Time

24 SEP 2020 12:36

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**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 98.3 °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	24 SEP 2020 19:51
PC Open Date & Time	24 SEP 2020 13:31
PC Close Date & Time	25 SEP 2020 11:59



US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**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

100.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 12:31

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

27 SEP 2020 04:57

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

27 SEP 2020 12:20

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**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

28 SEP 2020 16:34

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:46

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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

98.5 °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

29 SEP 2020 16:55

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**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

98.5 °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

30 SEP 2020 16:38

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 10:20

PC Open Date & Time

24 SEP 2020 10:06

PC Close Date & Time

24 SEP 2020 12:36

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**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

24 SEP 2020 19:51

PC Open Date & Time

24 SEP 2020 13:31

PC Close Date & Time

25 SEP 2020 11:59



US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**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

25 SEP 2020 12:32

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 04:58

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**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

27 SEP 2020 12:20

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**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

28 SEP 2020 16:35

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:46

**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

29 SEP 2020 16:55

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**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

30 SEP 2020 16:38

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**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 ☐

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 10:21
PC Open Date & Time	24 SEP 2020 10:06
PC Close Date & Time	24 SEP 2020 12:36



US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**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 ☐

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 19:51
PC Open Date & Time	24 SEP 2020 13:31
PC Close Date & Time	25 SEP 2020 11:59

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**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 ☒

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:46

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 12:33
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:46

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:46

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 04:58
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

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 ☒

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 12:20
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59



US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:46

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 16:35
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:46

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:46

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 16:55
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:46

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 16:38
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3022246

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022246

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3022246

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3022246

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022246

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022246

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022246

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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

US3022246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 OCT 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 09:05
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022246

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 OCT 2020

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

US3022246

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 OCT 2020

Collection time (00:00-23:59)

09:18 (24 HR)

Collection date and time (derived)

20 OCT 2020 09:18



US3022246

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

21 OCT 2020 05:29:19

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3022246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 OCT 2020 12:45:24

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3022246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 NOV 2020 12:01:16

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3022246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

18 NOV 2020 07:01:36

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 11:21:47
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 DEC 2020 09:56:49

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

06 DEC 2020 09:32:16

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59



US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

13 DEC 2020 09:53:45

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

20 DEC 2020 09:00:25

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

27 DEC 2020 07:28:06

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

03 JAN 2021 07:46:23

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

10 JAN 2021 13:03:14

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 05:56:01

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

24 JAN 2021 09:19:11

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

31 JAN 2021 09:28:52

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59



US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

07 FEB 2021 07:29:56

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

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	14 FEB 2021 08:49:51
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

21 FEB 2021 09:08:00

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

28 FEB 2021 14:08:32

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

07 MAR 2021 09:08:52

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

14 MAR 2021 08:10:46

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 MAR 2021 12:27:51

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

28 MAR 2021 10:06:54

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59



US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

04 APR 2021 09:04:01

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

11 APR 2021 12:35:34

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

18 APR 2021 08:07:48

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

25 APR 2021 09:04:52

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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

02 MAY 2021 07:37:27

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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[Patient Cloud Close Date & Time](#)

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10 JUN 2021 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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[Patient Cloud Close Date & Time](#)

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24 JUN 2021 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

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"/>

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

04 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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11 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUL 2021 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

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"/>

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	25 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUL 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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[Patient Cloud Close Date & Time](#)

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26 AUG 2021 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

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"/>

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

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 <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"/>

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59
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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

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"/>

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

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

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



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	05 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59
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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

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"/>



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

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 <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"/>

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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[Patient Cloud Close Date & Time](#)

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17 MAR 2022 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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03 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 APR 2022 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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[Patient Cloud Close Date & Time](#)

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14 APR 2022 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	17 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 APR 2022 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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°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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JUN 2022 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 691

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

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

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

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

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

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



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

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"/>



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

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"/>

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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25 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 SEP 2022 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 OCT 2022 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

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

09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

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US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	16 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2022 23:59

US3022246

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**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 ☐

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	23 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2022 23:59

US3022246

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:50:46

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		28 FEB 2021 14:08:46



US3022246

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022246

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022246

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022246

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022246

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022246

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022246

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022246

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:25:45

Generated On: 09 Jun 2021 14:50:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3022246

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 23:08:47

Generated On: 09 Jun 2021 14:50:46

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3022246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 22:21:53

Generated On: 09 Jun 2021 14:50:46

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) \_\_\_\_\_

US3022246

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 23:08:47

Generated On: 09 Jun 2021 14:50:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 MAR 2021

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

US3022246

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 23:08:47

Generated On: 09 Jun 2021 14:50:46

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 MAR 2021
Collection time (00:00-23:59)	09:43 (24 HR)
Collection date and time (derived)	09 MAR 2021 09:43

US3022246

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 23:08:47

Generated On: 09 Jun 2021 14:50:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022246

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 11:19:52

Generated On: 09 Jun 2021 14:50:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022246

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 11:19:51

Generated On: 09 Jun 2021 14:50:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3022246**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

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*



**US3022246**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3022246

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:50:46

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"/>

**US3022246**

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

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

**Generated On: 09 Jun 2021 14:50:46**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3022246

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

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:25:44

Generated On: 09 Jun 2021 14:50:46

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

Visit date (dd MMM yyyy)	27 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3022246

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

Form: Unblinding

Data signed: (b) (4) 25 Mar 2021 23:08:47

Generated On: 09 Jun 2021 14:50:46

Date of updated informed consent (dd MMM yyyy) 27 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 27 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3022246

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 00:25:44

Generated On: 09 Jun 2021 14:50:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 JAN 2021

Collection time (00:00-23:59)

14:27 (24 HR)

Collection date and time (derived)

27 JAN 2021 14:27

US3022246

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Feb 2021 00:25:44

Generated On: 09 Jun 2021 14:50:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 JAN 2021

Collection time (00:00 - 23:59)

14:44

Collection Date and Time (derived)

27 JAN 2021 14:44

US3022246

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 24 Feb 2021 00:25:42

Generated On: 09 Jun 2021 14:50:46

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3022246

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Feb 2021 00:25:42

Generated On: 09 Jun 2021 14:50:46

AEID	USA-US051-2020-MRNA-1273-P30 1000011
Adverse event	WORSENING OF LEFT HIP OSTEOARTHRITIS
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)	14 NOV 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)	15 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	14 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	15 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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US3022246

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Feb 2021 00:25:42

Generated On: 09 Jun 2021 14:50:46

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	PRE-PLANNED SURGERY DUE TO WORSENING OF LEFT HIP ARTHRITIS.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 24 Feb 2021 00:25:43

Generated On: 09 Jun 2021 14:50:46

---

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

Yes ☒

No ☐

---

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

---

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 22:21:53

Generated On: 09 Jun 2021 14:50:46

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 22:21:53

Generated On: 09 Jun 2021 14:50:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
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"/>

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 22:21:53

Generated On: 09 Jun 2021 14:50:46

Name of Medication LEVOTHYROIXINE

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM

Dose per administration 88

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 22:21:53

Generated On: 09 Jun 2021 14:50:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 22:21:53

Generated On: 09 Jun 2021 14:50:46

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP OSTEOARTHRITIS

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 22:21:53

Generated On: 09 Jun 2021 14:50:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 22:21:53

Generated On: 09 Jun 2021 14:50:46

Name of Medication OXYCODONE  
ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication WORSENING OF LEFT HIP  
ARTHRITIS

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 22:21:53

Generated On: 09 Jun 2021 14:50:46

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

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 22:21:53

Generated On: 09 Jun 2021 14:50:46

Name of Medication COLACE STOOL SOFTENER

Prophylaxis Yes ☐  
No ☒

Indication WORSENING OF LEFT  
OSTEOARTHRITIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 22:21:53

Generated On: 09 Jun 2021 14:50:46

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

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 22:21:53

Generated On: 09 Jun 2021 14:50:46

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 22:21:53

Generated On: 09 Jun 2021 14:50:46

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 22:21:53

Generated On: 09 Jun 2021 14:50:46

Name of Medication PRIMAXIN

Prophylaxis Yes ☐  
No ☒

Indication WORSENING OF LEFT HIP  
OSTEOARTHRITIS

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

335 of 1796



US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 22:21:53

Generated On: 09 Jun 2021 14:50:46

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

US3022246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 24 Feb 2021 00:25:43

Generated On: 09 Jun 2021 14:50:46

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3022246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 24 Feb 2021 00:25:43

Generated On: 09 Jun 2021 14:50:46

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
14 NOV 2020	LEFT HIP RELACEMENT	Adverse Event	

US3022246

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:50:46

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

US3022246

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:50:46

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 ☐

US3022246

Folder: SAE USA-US051-2020-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 24 Feb 2021 00:25:44

Generated On: 09 Jun 2021 14:50:46

SAEID	USA-US051-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3022246

Folder: SAE USA-US051-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Feb 2021 00:25:44

Generated On: 09 Jun 2021 14:50:46

SAEID	USA-US051-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/NOV/2020 16:12
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

US3022246

Folder: SAE USA-US051-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Feb 2021 00:25:44

Generated On: 09 Jun 2021 14:50:46

SAEID	USA-US051-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	25/NOV/2020 14:44
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



US3022246

Folder: SAE USA-US051-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Feb 2021 00:25:44

Generated On: 09 Jun 2021 14:50:46

SAEID	USA-US051-2020-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	14/JAN/2021 12:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3022246 (Prod: Meridian Clinical Research-Savannah)

**US3022246**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 14:50:46**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
User entered 'US3022246'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 12:19:11

**US3022246**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 17:42:35
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '21 AUG 2020'	RWS_ENDPOINT	21 Aug 2020 12:19:12
	ENDPOINT (b) (4)	
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Clinic (Clinic)'	(b) (4) Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:42:35

**US3022246**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered 'SCRN'	(b) (4), (b) (6) System	21 Aug 2020 17:42:35

US3022246

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:46

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered (b) (6) 1958'	RWS_ENDPOINT	21 Aug 2020 12:19:13
	ENDPOINT (b) (4)	
	(b) (4)	



US3022246

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:46

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '62'	Stella Yoon (b) (4)	21 Aug 2020 17:42:51
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:46**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered 'YEARS'	(b) (4), (b) (6) System	21 Aug 2020 17:42:51

**US3022246**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:46**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered '62'	(b) (4), (b) (6) System	21 Aug 2020 13:39:33

**US3022246**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:46**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Male (M)'	Stella Yoon (b) (4)	21 Aug 2020 17:42:51
	(b) (4)	

US3022246

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:46

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Stella Yoon (b) (4)	21 Aug 2020 17:42:51
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:46**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'I'	Stella Yoon (b) (4)	21 Aug 2020 17:42:51
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:46**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 17:42:51
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:46**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 17:42:51
	(b) (4)	



**US3022246**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:46**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 17:42:51
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:46**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 17:42:51
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:46**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 17:42:51
	(b) (4)	

US3022246

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:50:46

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 17:42:51
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:46**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 17:42:51
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:50:46**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 17:42:51
	(b) (4)	

US3022246

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:46

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '21 Aug 2020'	Shanice Bennett (b) (4)	21 Aug 2020 13:39:33
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered 'Aug 2020'	(b) (4), (b) (6) System	21 Aug 2020 13:39:33



**US3022246**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered '2020'	(b) (4), (b) (6) System	21 Aug 2020 13:39:33

**US3022246**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:50:46**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Amendment 2 (2)'	Shanice Bennett (b) (4)	21 Aug 2020 13:39:33
	(b) (4)	

US3022246

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	21 Aug 2020 13:39:33
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:50:46**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	21 Aug 2020 13:39:33
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:50:46**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	21 Aug 2020 13:39:33
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:50:46**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	21 Aug 2020 13:39:33
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:50:46**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	RWS_ENDPOINT	21 Aug 2020 12:19:12
	ENDPOINT (b) (4)	
	(b) (4)	

US3022246

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:50:46

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered 'I'	(b) (4), (b) (6) System	21 Aug 2020 13:39:33



US3022246

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	21 Aug 2020 13:33:17
	(b) (4)	

US3022246

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:50:46

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 17:43:04
	(b) (4)	

US3022246

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:50:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:45:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:45:22
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 17:44:00
User entered 'hyperlipidemia'	Stella Yoon (b) (4)	21 Aug 2020 17:43:20
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'un UNK 2010'	Stella Yoon (b) (4)	21 Aug 2020 17:43:20
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 17:43:20
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 17:43:20
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 17:43:20
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 17:43:20
	(b) (4)	



**US3022246**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered 'Jan 2010'	(b) (4), (b) (6) System	21 Aug 2020 17:43:20

**US3022246**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered '2010'	(b) (4), (b) (6) System	21 Aug 2020 17:43:20

**US3022246**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 17:43:20

**US3022246**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 17:43:20

US3022246

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:50:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:45:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 17:45:22
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 17:44:00
User entered 'hypothyroidism'	Stella Yoon (b) (4)	21 Aug 2020 17:43:29
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'un UNK 2015'	Stella Yoon (b) (4)	21 Aug 2020 17:43:29
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:50:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 17:43:29
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:50:46**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 17:43:29
	(b) (4)	



**US3022246**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 17:43:29
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:50:46**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 17:43:29
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered 'Jan 2015'	(b) (4), (b) (6) System	21 Aug 2020 17:43:29

**US3022246**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered '2015'	(b) (4), (b) (6) System	21 Aug 2020 17:43:29

**US3022246**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 17:43:29

**US3022246**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 17:43:29

US3022246

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:50:46

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Coxarthrosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Dec 2020 19:43:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Dec 2020 19:43:56
Data point term sent to Coder	System	09 Dec 2020 19:43:41
Coding entries removed.	Shanice Bennett (b) (4)	09 Dec 2020 19:43:37
User entered 'LEFT HIP ARTHRITIS' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	09 Dec 2020 19:43:37
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	13 Nov 2020 19:31:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	13 Nov 2020 19:31:48
Data point term sent to Coder	System	13 Nov 2020 19:31:06
User entered 'left hip osteoarthritis'	(b) (4), (b) (6)	13 Nov 2020 19:30:20

**US3022246**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'UN UNK 2010' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:28:15
User entered 'un UNK 2019'	(b) (4), (b) (6)	13 Nov 2020 19:30:20



**US3022246**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:50:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 19:30:20

**US3022246**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:50:46**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 19:30:20

**US3022246**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:30:20

**US3022246**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:50:46**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 19:30:20

**US3022246**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered 'Jan 2010'	(b) (4), (b) (6)	
	System	24 Nov 2020 20:28:15
User entered 'Jan 2019'	System	13 Nov 2020 19:30:20

**US3022246**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User entered '2010'	System	24 Nov 2020 20:28:15
User entered '2019'	System	13 Nov 2020 19:30:20

**US3022246**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered empty.	(b) (4), (b) (6) System	13 Nov 2020 19:30:20

**US3022246**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered empty.	(b) (4), (b) (6) System	13 Nov 2020 19:30:20



**US3022246**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 17:44:23
	(b) (4)	

US3022246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '21 Aug 2020'	Stella Yoon (b) (4)	21 Aug 2020 17:44:23
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '8:24'	Stella Yoon (b) (4)	21 Aug 2020 17:44:23
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered '21 Aug 2020 8:24'	(b) (4), (b) (6) System	21 Aug 2020 17:44:23

**US3022246**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '169' cm	Stella Yoon (b) (4)	21 Aug 2020 17:44:23
	(b) (4)	
DataPoint set to visible.	System	21 Aug 2020 13:39:33

US3022246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '98.3' kg	Stella Yoon (b) (4)	21 Aug 2020 17:44:23
	(b) (4)	
DataPoint set to visible.	System	21 Aug 2020 13:39:33

**US3022246**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
Amendment Manager: User entered '34.41756'	(b) (4), (b) (6)	
User entered '34.4'	System	17 Sep 2020 00:17:35
DataPoint set to visible.	System	21 Aug 2020 17:44:23
	System	21 Aug 2020 13:39:33

US3022246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	21 Aug 2020 17:44:23
DataPoint set to visible.	System	21 Aug 2020 13:39:33



US3022246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
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 the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 05:55:09
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 the units should not remain. Please review and update as appropriate. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 15:58:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 15:58:44
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 the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 11:11:45
User entered '36.8' C	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:44:23

US3022246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 15:58:44
User entered 'Oral (Oral)'	Stella Yoon (b) (4)	21 Aug 2020 17:44:23
	(b) (4)	

US3022246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 17:44:23
	(b) (4)	

US3022246

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 15:58:44
User entered '68'	Stella Yoon (b) (4)	21 Aug 2020 17:44:23
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered 'bpm'	(b) (4), (b) (6) System	21 Aug 2020 17:44:23

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Folder: Screening

Form: Vital Signs

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 15:58:44
User entered '17'	Stella Yoon (b) (4)	21 Aug 2020 17:44:23
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered 'breaths/min'	(b) (4), (b) (6) System	21 Aug 2020 17:44:23

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 15:58:44
User entered '139'	Stella Yoon (b) (4)	21 Aug 2020 17:44:23
	(b) (4)	



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Folder: Screening

Form: Vital Signs

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[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 17:44:23

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 15:58:44
User entered '87'	Stella Yoon (b) (4)	21 Aug 2020 17:44:23
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 17:44:23

**US3022246**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:37:32

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:37:32

US3022246

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 17:44:27
	(b) (4)	

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '21 Aug 2020'	Stella Yoon (b) (4)	21 Aug 2020 17:44:27
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	

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Folder: Screening

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**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)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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**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)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[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)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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**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)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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**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)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[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)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

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**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)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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**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)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	

**US3022246**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 14:50:46**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'network computer technician - exposed to many clients in the field'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:46

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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**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)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:46

[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)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

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**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)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'I'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'I'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:50:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:37:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'lives in community with ongoing person to person transmission'	Stella Yoon (b) (4)	21 Aug 2020 17:45:04
	(b) (4)	

**US3022246**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 17:45:12

**US3022246**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '21 Aug 2020'	Stella Yoon (b) (4)	21 Aug 2020 17:45:12

**US3022246**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

[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 16:43:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Clinic (Clinic)'	Stella Yoon (b) (4)	21 Aug 2020 17:45:12

**US3022246**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'VISIT1'	System	21 Aug 2020 17:45:12



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 12:59:29

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '106834'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 12:59:29

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 12:59:29

US3022246

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:46

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 16:43:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 17:45:22

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:46

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 16:43:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 17:45:22

US3022246

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 17:45:22

**US3022246**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 17:45:22

US3022246

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:50:46

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:45:22



US3022246

Folder: Visit 1 Day 1

Form: Randomization

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Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 11:41:58
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 18:49:51
User entered 'No (N)'	Morgan Deal (b) (4)	12 Nov 2020 18:49:46
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	28 Oct 2020 18:25:15
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:37:50
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:55:11

US3022246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 06:47:18
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 15:59:36
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 15:59:27
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:58:55
User entered '169' cm	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:46:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 15:59:27
User entered '98.3' kg	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

US3022246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 06:47:18
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 15:59:36
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 15:59:27
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:58:55
User entered '169' cm	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:46:29

US3022246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 15:59:27
User entered '98.3' kg	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

US3022246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

US3022246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '21 Aug 2020'	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	



**US3022246**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '08:24'	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered '21 Aug 2020 08:24'	(b) (4), (b) (6) System	21 Aug 2020 17:46:29

US3022246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '36.8' C	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Oral (Oral)'	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

**US3022246**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '68'	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'bpm'	(b) (4), (b) (6) System	21 Aug 2020 17:46:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '17'	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'breaths/min'	(b) (4), (b) (6) System	21 Aug 2020 17:46:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '139'	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 17:46:29

US3022246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '87'	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 17:46:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 06:47:18
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 15:59:36
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 15:59:27
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:58:55
User entered '169' cm	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:46:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:50:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 15:59:27
User entered '98.3' kg	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:46:29



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '21 Aug 2020'	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

**US3022246**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '09:50'	(b) (4) Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:46:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered '21 Aug 2020 09:50'	(b) (4), (b) (6) System	21 Aug 2020 17:46:29

US3022246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '37.0' C	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Oral (Oral)'	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '83'	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'bpm'	(b) (4), (b) (6) System	21 Aug 2020 17:46:29

US3022246

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '14'	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'breaths/min'	(b) (4), (b) (6) System	21 Aug 2020 17:46:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '140'	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 17:46:29

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '89'	Stella Yoon (b) (4)	21 Aug 2020 17:46:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'mmHg'	(b) (4), (b) (6) System	21 Aug 2020 17:46:29

US3022246

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 17:46:34
	(b) (4)	



**US3022246**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:50:46**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '21 Aug 2020'	Stella Yoon (b) (4)	21 Aug 2020 17:46:34
	(b) (4)	

**US3022246**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:50:46**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4)	21 Aug 2020 13:40:05

**US3022246**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:50:46**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	21 Aug 2020 13:40:05
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:46

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 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered empty.	(b) (4) Shanice Bennett (b) (4)	21 Aug 2020 13:40:05
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '21 Aug 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	21 Aug 2020 13:40:05

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '09:19'	(b) (4) Shanice Bennett (b) (4) (b) (4)	21 Aug 2020 13:40:05

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered '21 Aug 2020 09:19'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Shanice Bennett (b) (4)	21 Aug 2020 13:40:05
	(b) (4)	

US3022246

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'ONCE'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:50:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 17:46:52
	(b) (4)	

US3022246

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '21 Aug 2020'	Stella Yoon (b) (4)	21 Aug 2020 17:46:52
	(b) (4)	

**US3022246**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:46**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '08:30'	Stella Yoon (b) (4)	21 Aug 2020 17:46:52
	(b) (4)	

**US3022246**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered '21 Aug 2020 08:30'	(b) (4), (b) (6) System	21 Aug 2020 17:46:52

**US3022246**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 14:50:46**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '21 Aug 2020'	Stella Yoon (b) (4)	21 Aug 2020 17:47:05
	(b) (4)	



US3022246

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:47:05

US3022246

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 17:47:05
	(b) (4)	

**US3022246**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '08:27'	Stella Yoon (b) (4)	21 Aug 2020 17:47:05
	(b) (4)	

**US3022246**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered '21 Aug 2020 08:27'	(b) (4), (b) (6) System	21 Aug 2020 17:47:05

**US3022246**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:50:46**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:47:05

US3022246

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:50:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 17:47:05
	(b) (4)	

**US3022246**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:47:05

**US3022246**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered empty.	(b) (4), (b) (6) System	21 Aug 2020 17:47:05



US3022246

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 17:47:15
	(b) (4)	

**US3022246**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'I'	(b) (4), (b) (6) System	21 Aug 2020 17:47:15

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T09:50:43', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '5cdae133-4003-41af-8579-03257121a74d' User entered 'Yes (Y)'	(b) (4), (b) (6) System	21 Aug 2020 13:51:12
	System	21 Aug 2020 13:51:12

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T09:50:57', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '5cdae133-4003-41af-8579-03257121a74d' User entered '98.6'	(b) (4), (b) (6) System	21 Aug 2020 13:51:12
	System	21 Aug 2020 13:51:12

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T09:51:02', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '5cdae133-4003-41af-8579-03257121a74d' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 13:51:12
	System	21 Aug 2020 13:51:12

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T09:51:10', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '5cdae133-4003-41af-8579-03257121a74d' User entered '21 Aug 2020 09:51'	(b) (4), (b) (6) System	21 Aug 2020 13:51:12
	System	21 Aug 2020 13:51:12

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '21 Aug 2020 09:39'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05



**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '21 Aug 2020 12:09'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T18:51:44', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '9801b331-3a18-43e4-a355-73e032f28dbb' User entered 'Yes (Y)'	(b) (4), (b) (6) System	21 Aug 2020 22:52:06
	System	21 Aug 2020 22:52:06

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T18:51:51', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '9801b331-3a18-43e4-a355-73e032f28dbb' User entered '97.7'	(b) (4), (b) (6) System	21 Aug 2020 22:52:06
	System	21 Aug 2020 22:52:06

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T18:51:57', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '9801b331-3a18-43e4-a355-73e032f28dbb' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 22:52:06
	System	21 Aug 2020 22:52:06

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T18:52:03', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '9801b331-3a18-43e4-a355-73e032f28dbb' User entered '21 Aug 2020 18:52'	(b) (4), (b) (6) System	21 Aug 2020 22:52:06
	System	21 Aug 2020 22:52:06

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '21 Aug 2020 13:04'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05



US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 2'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-22T21:00:48', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '5892a4d0-92d3-4e60-8b86-2d5c9904d74a' User entered 'Yes (Y)'	(b) (4), (b) (6) System	23 Aug 2020 01:01:18
	System	23 Aug 2020 01:01:18

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-22T21:01:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '5892a4d0-92d3-4e60-8b86-2d5c9904d74a' User entered '97.6'	(b) (4), (b) (6) System	23 Aug 2020 01:01:18
	System	23 Aug 2020 01:01:18

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-22T21:01:07', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '5892a4d0-92d3-4e60-8b86-2d5c9904d74a'	(b) (4), (b) (6)	23 Aug 2020 01:01:18
User entered 'No (N)'	System	23 Aug 2020 01:01:18

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-22T21:01:15', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '5892a4d0-92d3-4e60-8b86-2d5c9904d74a' User entered '22 Aug 2020 21:01'	(b) (4), (b) (6) System	23 Aug 2020 01:01:18
	System	23 Aug 2020 01:01:18

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 3'	System	21 Aug 2020 13:40:05



US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-23T18:51:51', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '61b44488-b2a3-4ba6-add2-393364210114' User entered 'Yes (Y)'	(b) (4), (b) (6) System	23 Aug 2020 22:52:20
	System	23 Aug 2020 22:52:20

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-23T18:52:05', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '61b44488-b2a3-4ba6-add2-393364210114' User entered '98.1'	(b) (4), (b) (6) System	23 Aug 2020 22:52:20
	System	23 Aug 2020 22:52:20

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-23T18:52:08', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '61b44488-b2a3-4ba6-add2-393364210114' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 22:52:20
	System	23 Aug 2020 22:52:20

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-23T18:52:18', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '61b44488-b2a3-4ba6-add2-393364210114' User entered '23 Aug 2020 18:52'	(b) (4), (b) (6) System	23 Aug 2020 22:52:20
	System	23 Aug 2020 22:52:20

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 4'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-24T18:12:59', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '999480f9-4f54-4fd1-a197-99efdf703d23' User entered 'Yes (Y)'	(b) (4), (b) (6) System	24 Aug 2020 22:13:25
	System	24 Aug 2020 22:13:25



US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-24T18:13:11', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '999480f9-4f54-4fd1-a197-99efdf703d23' User entered '98.0'	(b) (4), (b) (6) System	24 Aug 2020 22:13:25
	System	24 Aug 2020 22:13:25

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-24T18:13:15', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '999480f9-4f54-4fd1-a197-99efdf703d23'	(b) (4), (b) (6)	24 Aug 2020 22:13:25
User entered 'No (N)'	System	24 Aug 2020 22:13:25

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-24T18:13:23', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '999480f9-4f54-4fd1-a197-99efdf703d23' User entered '24 Aug 2020 18:13'	(b) (4), (b) (6) System	24 Aug 2020 22:13:25
	System	24 Aug 2020 22:13:25

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 5'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-25T12:41:44', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'a693f8ad-bccb-48e6-957c-65fcca4eac1a' User entered 'Yes (Y)'	(b) (4), (b) (6) System	25 Aug 2020 16:42:11
	System	25 Aug 2020 16:42:11

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-25T12:41:54', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'a693f8ad-bccb-48e6-957c-65fcca4eac1a' User entered '98.6'	(b) (4), (b) (6) System	25 Aug 2020 16:42:11
	System	25 Aug 2020 16:42:11



US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-25T12:42:01', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'a693f8ad-bccb-48e6-957c-65fcca4eac1a' User entered 'No (N)'	(b) (4), (b) (6) System	25 Aug 2020 16:42:11
	System	25 Aug 2020 16:42:11

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-25T12:42:05', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'a693f8ad-bccb-48e6-957c-65fcca4eac1a' User entered '25 Aug 2020 12:42'	(b) (4), (b) (6) System	25 Aug 2020 16:42:11
	System	25 Aug 2020 16:42:11

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 6'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-26T13:32:35', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '4439494e-053b-4a95-9532-29f4cafadfa9' User entered 'Yes (Y)'	(b) (4), (b) (6) System	26 Aug 2020 17:32:51
	System	26 Aug 2020 17:32:51

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-26T13:32:42', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '4439494e-053b-4a95-9532-29f4cafadfa9' User entered '98.7'	(b) (4), (b) (6) System	26 Aug 2020 17:32:51
	System	26 Aug 2020 17:32:51

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-26T13:32:45', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '4439494e-053b-4a95-9532-29f4cafadfa9' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 17:32:51
	System	26 Aug 2020 17:32:51



**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-26T13:32:49', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '4439494e-053b-4a95-9532-29f4cafadfa9' User entered '26 Aug 2020 13:32'	(b) (4), (b) (6) System	26 Aug 2020 17:32:51
	System	26 Aug 2020 17:32:51

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 7'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-27T12:15:58', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'd2610f2a-0f20-4e33-8cf3-3d46bd42688c' User entered 'Yes (Y)'	(b) (4), (b) (6) System	27 Aug 2020 16:17:30
	System	27 Aug 2020 16:17:30

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-27T12:17:19', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'd2610f2a-0f20-4e33-8cf3-3d46bd42688c' User entered '98.5'	(b) (4), (b) (6) System	27 Aug 2020 16:17:30
	System	27 Aug 2020 16:17:30

US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-27T12:17:22', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'd2610f2a-0f20-4e33-8cf3-3d46bd42688c' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 16:17:30
	System	27 Aug 2020 16:17:30

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-27T12:17:28', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'd2610f2a-0f20-4e33-8cf3-3d46bd42688c' User entered '27 Aug 2020 12:17'	(b) (4), (b) (6) System	27 Aug 2020 16:17:30
	System	27 Aug 2020 16:17:30



US3022246

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '27 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T09:51:24', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'cdfef030a-d96f-4405-a0de-c8f4e721aca4' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 13:51:44
	System	21 Aug 2020 13:51:44

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T09:51:28', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'cdf030a-d96f-4405-a0de-c8f4e721aca4' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 13:51:44
	System	21 Aug 2020 13:51:44

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T09:51:33', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'cdf030a-d96f-4405-a0de-c8f4e721aca4' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 13:51:44
	System	21 Aug 2020 13:51:44

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T09:51:37', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'cdfef030a-d96f-4405-a0de-c8f4e721aca4' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 13:51:44
	System	21 Aug 2020 13:51:44

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T09:51:42', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'cdf030a-d96f-4405-a0de-c8f4e721aca4' User entered '21 Aug 2020 09:51'	(b) (4), (b) (6) System	21 Aug 2020 13:51:44
	System	21 Aug 2020 13:51:44



US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '21 Aug 2020 09:39'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '21 Aug 2020 12:09'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T18:52:33', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '08c7cabd-ff62-4e37-908c-f5e233a1449b' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 22:53:13
	System	21 Aug 2020 22:53:13

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T18:52:37', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '08c7cabd-ff62-4e37-908c-f5e233a1449b' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 22:53:13
	System	21 Aug 2020 22:53:13

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T18:52:51', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '08c7cabd-ff62-4e37-908c-f5e233a1449b' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 22:53:13
	System	21 Aug 2020 22:53:13

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T18:53:04', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '08c7cabd-ff62-4e37-908c-f5e233a1449b' User entered 'None (1)'	(b) (4), (b) (6) System	21 Aug 2020 22:53:13
	System	21 Aug 2020 22:53:13

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T18:53:12', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '08c7cabd-ff62-4e37-908c-f5e233a1449b' User entered '21 Aug 2020 18:53'	(b) (4), (b) (6) System	21 Aug 2020 22:53:13
	System	21 Aug 2020 22:53:13



**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '21 Aug 2020 13:04'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 2'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-22T21:01:31', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '98dd86c1-bf1e-48f8-ac9a-31be859b0c4c' User entered 'None (1)'	(b) (4), (b) (6) System	23 Aug 2020 01:02:05
	System	23 Aug 2020 01:02:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-22T21:01:36', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '98dd86c1-bf1e-48f8-ac9a-31be859b0c4c' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 01:02:05
	System	23 Aug 2020 01:02:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-22T21:01:47', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '98dd86c1-bf1e-48f8-ac9a-31be859b0c4c' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 01:02:05
	System	23 Aug 2020 01:02:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-22T21:01:56', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '98dd86c1-bf1e-48f8-ac9a-31be859b0c4c' User entered 'None (1)'	(b) (4), (b) (6) System	23 Aug 2020 01:02:05
	System	23 Aug 2020 01:02:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-22T21:02:02', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '98dd86c1-bf1e-48f8-ac9a-31be859b0c4c' User entered '22 Aug 2020 21:02'	(b) (4), (b) (6) System	23 Aug 2020 01:02:05
	System	23 Aug 2020 01:02:05



**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 3'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-23T18:52:27', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '41262a1a-2cc7-4da9-96d0-17cf04e4a883' User entered 'None (1)'	(b) (4), (b) (6) System	23 Aug 2020 22:52:57
	System	23 Aug 2020 22:52:57

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-23T18:52:32', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '41262a1a-2cc7-4da9-96d0-17cf04e4a883' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 22:52:57
	System	23 Aug 2020 22:52:57

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-23T18:52:38', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '41262a1a-2cc7-4da9-96d0-17cf04e4a883' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 22:52:57
	System	23 Aug 2020 22:52:57

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-23T18:52:49', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '41262a1a-2cc7-4da9-96d0-17cf04e4a883' User entered 'None (1)'	(b) (4), (b) (6) System	23 Aug 2020 22:52:57
	System	23 Aug 2020 22:52:57

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-23T18:52:56', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '41262a1a-2cc7-4da9-96d0-17cf04e4a883' User entered '23 Aug 2020 18:52'	(b) (4), (b) (6) System	23 Aug 2020 22:52:57
	System	23 Aug 2020 22:52:57



US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 4'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-24T18:13:34', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '0bb27575-2696-459d-9ecf-c9af9c690318' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 22:14:00
	System	24 Aug 2020 22:14:00

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-24T18:13:37', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '0bb27575-2696-459d-9ecf-c9af9c690318' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 22:14:00
	System	24 Aug 2020 22:14:00

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-24T18:13:41', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '0bb27575-2696-459d-9ecf-c9af9c690318' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 22:14:00
	System	24 Aug 2020 22:14:00

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-24T18:13:49', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '0bb27575-2696-459d-9ecf-c9af9c690318' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 22:14:00
	System	24 Aug 2020 22:14:00

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-24T18:13:54', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '0bb27575-2696-459d-9ecf-c9af9c690318' User entered '24 Aug 2020 18:13'	(b) (4), (b) (6) System	24 Aug 2020 22:14:00
	System	24 Aug 2020 22:14:00



**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 5'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-25T12:42:12', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '7bda9259-d31c-451b-b949-6482e2342bd4'	(b) (4), (b) (6) System	25 Aug 2020 16:42:30
User entered 'None (1)'	System	25 Aug 2020 16:42:30

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-25T12:42:15', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '7bda9259-d31c-451b-b949-6482e2342bd4' User entered 'No (N)'	(b) (4), (b) (6) System	25 Aug 2020 16:42:30
	System	25 Aug 2020 16:42:30

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-25T12:42:18', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '7bda9259-d31c-451b-b949-6482e2342bd4' User entered 'No (N)'	(b) (4), (b) (6) System	25 Aug 2020 16:42:30
	System	25 Aug 2020 16:42:30

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-25T12:42:22', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '7bda9259-d31c-451b-b949-6482e2342bd4'	(b) (4), (b) (6) System	25 Aug 2020 16:42:30
User entered 'None (1)'	System	25 Aug 2020 16:42:30

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-25T12:42:26', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '7bda9259-d31c-451b-b949-6482e2342bd4' User entered '25 Aug 2020 12:42'	(b) (4), (b) (6) System	25 Aug 2020 16:42:30
	System	25 Aug 2020 16:42:30



US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 6'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-26T13:32:56', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '08e7ae6a-6ebf-4eff-8053-c20706f81220' User entered 'None (1)'	(b) (4), (b) (6) System	26 Aug 2020 17:33:11
	System	26 Aug 2020 17:33:11

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-26T13:32:59', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '08e7ae6a-6ebf-4eff-8053-c20706f81220' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 17:33:11
	System	26 Aug 2020 17:33:11

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-26T13:33:02', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '08e7ae6a-6ebf-4eff-8053-c20706f81220' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 17:33:11
	System	26 Aug 2020 17:33:11

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-26T13:33:06', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '08e7ae6a-6ebf-4eff-8053-c20706f81220' User entered 'None (1)'	(b) (4), (b) (6) System	26 Aug 2020 17:33:11
	System	26 Aug 2020 17:33:11

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-26T13:33:09', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '08e7ae6a-6ebf-4eff-8053-c20706f81220' User entered '26 Aug 2020 13:33'	(b) (4), (b) (6) System	26 Aug 2020 17:33:11
	System	26 Aug 2020 17:33:11



**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 7'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-27T12:17:35', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'c9c2e8ca-7584-4b32-9452-1f7c6bf7bbff' User entered 'None (1)'	(b) (4), (b) (6) System	27 Aug 2020 16:17:49
	System	27 Aug 2020 16:17:49

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-27T12:17:38', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'c9c2e8ca-7584-4b32-9452-1f7c6bf7bbff' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 16:17:49
	System	27 Aug 2020 16:17:49

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-27T12:17:40', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'c9c2e8ca-7584-4b32-9452-1f7c6bf7bbff' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 16:17:49
	System	27 Aug 2020 16:17:49

US3022246

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-27T12:17:43', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'c9c2e8ca-7584-4b32-9452-1f7c6bf7bbff' User entered 'None (1)'	(b) (4), (b) (6) System	27 Aug 2020 16:17:49
	System	27 Aug 2020 16:17:49

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-27T12:17:46', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'c9c2e8ca-7584-4b32-9452-1f7c6bf7bbff' User entered '27 Aug 2020 12:17'	(b) (4), (b) (6) System	27 Aug 2020 16:17:49
	System	27 Aug 2020 16:17:49



**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '27 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T09:51:50', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '69abf4f2-e532-40db-8a41-984bafd33cc4' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 13:52:13
	System	21 Aug 2020 13:52:13

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T09:51:53', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '69abf4f2-e532-40db-8a41-984bafd33cc4' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 13:52:13
	System	21 Aug 2020 13:52:13

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T09:51:54', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '69abf4f2-e532-40db-8a41-984bafd33cc4' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 13:52:13
	System	21 Aug 2020 13:52:13

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T09:51:56', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '69abf4f2-e532-40db-8a41-984bafd33cc4' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 13:52:13
	System	21 Aug 2020 13:52:13

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T09:51:58', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '69abf4f2-e532-40db-8a41-984bafd33cc4' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 13:52:13
	System	21 Aug 2020 13:52:13



US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T09:52:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '69abf4f2-e532-40db-8a41-984bafd33cc4' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 13:52:13
	System	21 Aug 2020 13:52:13

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T09:52:06', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '69abf4f2-e532-40db-8a41-984bafd33cc4' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 13:52:13
	System	21 Aug 2020 13:52:13

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T09:52:09', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '69abf4f2-e532-40db-8a41-984bafd33cc4' User entered '21 Aug 2020 09:52'	(b) (4), (b) (6) System	21 Aug 2020 13:52:13
	System	21 Aug 2020 13:52:13

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '21 Aug 2020 09:39'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '21 Aug 2020 12:09'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T18:53:20', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '36c50c0f-96fb-40d5-8638-eb2725e9efea' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 22:53:43
	System	21 Aug 2020 22:53:43

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T18:53:22', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '36c50c0f-96fb-40d5-8638-eb2725e9efea' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 22:53:43
	System	21 Aug 2020 22:53:43



US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T18:53:26', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '36c50c0f-96fb-40d5-8638-eb2725e9efea' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 22:53:43
	System	21 Aug 2020 22:53:43

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T18:53:29', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '36c50c0f-96fb-40d5-8638-eb2725e9efea' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 22:53:43
	System	21 Aug 2020 22:53:43

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T18:53:31', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '36c50c0f-96fb-40d5-8638-eb2725e9efea' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 22:53:43
	System	21 Aug 2020 22:53:43

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T18:53:33', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '36c50c0f-96fb-40d5-8638-eb2725e9efea' User entered 'None (0)'	(b) (4), (b) (6) System	21 Aug 2020 22:53:43
	System	21 Aug 2020 22:53:43

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T18:53:38', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '36c50c0f-96fb-40d5-8638-eb2725e9efea' User entered 'No (N)'	(b) (4), (b) (6) System	21 Aug 2020 22:53:43
	System	21 Aug 2020 22:53:43

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-21T18:53:41', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '36c50c0f-96fb-40d5-8638-eb2725e9efea' User entered '21 Aug 2020 18:53'	(b) (4), (b) (6) System	21 Aug 2020 22:53:43
	System	21 Aug 2020 22:53:43

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '21 Aug 2020 13:04'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05



US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 2'	System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-22T21:02:09', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '683732d4-f13f-4a71-b140-8c1192c8f41d' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 01:02:39
	System	23 Aug 2020 01:02:39

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-22T21:02:13', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '683732d4-f13f-4a71-b140-8c1192c8f41d' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 01:02:39
	System	23 Aug 2020 01:02:39

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-22T21:02:17', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '683732d4-f13f-4a71-b140-8c1192c8f41d' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 01:02:39
	System	23 Aug 2020 01:02:39

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-22T21:02:21', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '683732d4-f13f-4a71-b140-8c1192c8f41d' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 01:02:39
	System	23 Aug 2020 01:02:39

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-22T21:02:24', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '683732d4-f13f-4a71-b140-8c1192c8f41d' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 01:02:39
	System	23 Aug 2020 01:02:39

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-22T21:02:28', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '683732d4-f13f-4a71-b140-8c1192c8f41d' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 01:02:39
	System	23 Aug 2020 01:02:39

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-22T21:02:33', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '683732d4-f13f-4a71-b140-8c1192c8f41d' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 01:02:39
	System	23 Aug 2020 01:02:39



**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-22T21:02:36', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '683732d4-f13f-4a71-b140-8c1192c8f41d' User entered '22 Aug 2020 21:02'	(b) (4), (b) (6) System	23 Aug 2020 01:02:39
	System	23 Aug 2020 01:02:39

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 3'	System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-23T18:53:03', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'ace7cf49-4bf8-4bf6-8969-cfcde310d70b' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 22:53:30
	System	23 Aug 2020 22:53:30

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:46**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-23T18:53:06', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'ace7cf49-4bf8-4bf6-8969-cfcde310d70b' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 22:53:30
	System	23 Aug 2020 22:53:30

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-23T18:53:09', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'ace7cf49-4bf8-4bf6-8969-cfcde310d70b' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 22:53:30
	System	23 Aug 2020 22:53:30

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-23T18:53:13', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'ace7cf49-4bf8-4bf6-8969-cfcde310d70b' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 22:53:30
	System	23 Aug 2020 22:53:30



US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-23T18:53:15', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'ace7cf49-4bf8-4bf6-8969-cfcde310d70b' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 22:53:30
	System	23 Aug 2020 22:53:30

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:46

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-23T18:53:18', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'ace7cf49-4bf8-4bf6-8969-cfcde310d70b' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 22:53:30
	System	23 Aug 2020 22:53:30

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-23T18:53:23', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'ace7cf49-4bf8-4bf6-8969-cfcde310d70b' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 22:53:30
	System	23 Aug 2020 22:53:30

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-23T18:53:27', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'ace7cf49-4bf8-4bf6-8969-cfcde310d70b' User entered '23 Aug 2020 18:53'	(b) (4), (b) (6) System	23 Aug 2020 22:53:30
	System	23 Aug 2020 22:53:30

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 4'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-24T18:14:03', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '0968fc00-d1de-4430-b723-7086bcd253a0' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 22:14:33
	System	24 Aug 2020 22:14:33



US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-24T18:14:07', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '0968fc00-d1de-4430-b723-7086bcd253a0' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 22:14:33
	System	24 Aug 2020 22:14:33

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-24T18:14:12', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '0968fc00-d1de-4430-b723-7086bcd253a0' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 22:14:33
	System	24 Aug 2020 22:14:33

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-24T18:14:16', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '0968fc00-d1de-4430-b723-7086bcd253a0' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 22:14:33
	System	24 Aug 2020 22:14:33

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-24T18:14:19', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '0968fc00-d1de-4430-b723-7086bcd253a0' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 22:14:33
	System	24 Aug 2020 22:14:33

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:50:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-24T18:14:21', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '0968fc00-d1de-4430-b723-7086bcd253a0' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 22:14:33
	System	24 Aug 2020 22:14:33

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-24T18:14:26', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '0968fc00-d1de-4430-b723-7086bcd253a0' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 22:14:33
	System	24 Aug 2020 22:14:33

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-24T18:14:29', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '0968fc00-d1de-4430-b723-7086bcd253a0' User entered '24 Aug 2020 18:14'	(b) (4), (b) (6) System	24 Aug 2020 22:14:33
	System	24 Aug 2020 22:14:33

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05



**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 5'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-25T12:42:31', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f1dc8323-d224-4c16-a049-d3726ba2fc59' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 16:42:58
	System	25 Aug 2020 16:42:58

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-25T12:42:33', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f1dc8323-d224-4c16-a049-d3726ba2fc59' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 16:42:58
	System	25 Aug 2020 16:42:58

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-25T12:42:36', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f1dc8323-d224-4c16-a049-d3726ba2fc59' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 16:42:58
	System	25 Aug 2020 16:42:58

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-25T12:42:38', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f1dc8323-d224-4c16-a049-d3726ba2fc59' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 16:42:58
	System	25 Aug 2020 16:42:58

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-25T12:42:41', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f1dc8323-d224-4c16-a049-d3726ba2fc59' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 16:42:58
	System	25 Aug 2020 16:42:58

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-25T12:42:44', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f1dc8323-d224-4c16-a049-d3726ba2fc59' User entered 'None (0)'	(b) (4), (b) (6) System	25 Aug 2020 16:42:58
	System	25 Aug 2020 16:42:58



US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-25T12:42:48', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f1dc8323-d224-4c16-a049-d3726ba2fc59' User entered 'No (N)'	(b) (4), (b) (6) System	25 Aug 2020 16:42:58
	System	25 Aug 2020 16:42:58

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-25T12:42:51', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f1dc8323-d224-4c16-a049-d3726ba2fc59' User entered '25 Aug 2020 12:42'	(b) (4), (b) (6) System	25 Aug 2020 16:42:58
	System	25 Aug 2020 16:42:58

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 6'	System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-26T13:33:13', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '6ea6ad42-264b-49e2-afcf-8a1d49d78940' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 17:33:37
	System	26 Aug 2020 17:33:37

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-26T13:33:16', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '6ea6ad42-264b-49e2-afcf-8a1d49d78940' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 17:33:37
	System	26 Aug 2020 17:33:37

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-26T13:33:18', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '6ea6ad42-264b-49e2-afcf-8a1d49d78940' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 17:33:37
	System	26 Aug 2020 17:33:37



US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-26T13:33:21', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '6ea6ad42-264b-49e2-afcf-8a1d49d78940' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 17:33:37
	System	26 Aug 2020 17:33:37

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-26T13:33:23', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '6ea6ad42-264b-49e2-afcf-8a1d49d78940' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 17:33:37
	System	26 Aug 2020 17:33:37

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:46

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-26T13:33:26', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '6ea6ad42-264b-49e2-afcf-8a1d49d78940' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 17:33:37
	System	26 Aug 2020 17:33:37

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-26T13:33:29', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '6ea6ad42-264b-49e2-afcf-8a1d49d78940' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 17:33:37
	System	26 Aug 2020 17:33:37

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-26T13:33:33', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '6ea6ad42-264b-49e2-afcf-8a1d49d78940' User entered '26 Aug 2020 13:33'	(b) (4), (b) (6) System	26 Aug 2020 17:33:37
	System	26 Aug 2020 17:33:37

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 7'	System	21 Aug 2020 13:40:05



US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-27T12:17:51', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8493a80e-7644-4fa6-a062-a9877b0b4ff1' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 16:18:14
	System	27 Aug 2020 16:18:14

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-27T12:17:54', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8493a80e-7644-4fa6-a062-a9877b0b4ff1' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 16:18:14
	System	27 Aug 2020 16:18:14

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-27T12:17:56', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8493a80e-7644-4fa6-a062-a9877b0b4ff1' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 16:18:14
	System	27 Aug 2020 16:18:14

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-27T12:17:58', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8493a80e-7644-4fa6-a062-a9877b0b4ff1' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 16:18:14
	System	27 Aug 2020 16:18:14

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-27T12:18:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8493a80e-7644-4fa6-a062-a9877b0b4ff1' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 16:18:14
	System	27 Aug 2020 16:18:14

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-27T12:18:02', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8493a80e-7644-4fa6-a062-a9877b0b4ff1' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 16:18:14
	System	27 Aug 2020 16:18:14

US3022246

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-27T12:18:05', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8493a80e-7644-4fa6-a062-a9877b0b4ff1' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 16:18:14
	System	27 Aug 2020 16:18:14

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-08-27T12:18:09', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8493a80e-7644-4fa6-a062-a9877b0b4ff1' User entered '27 Aug 2020 12:18'	(b) (4), (b) (6) System	27 Aug 2020 16:18:14
	System	27 Aug 2020 16:18:14



**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '27 Aug 2020 12:00'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	21 Aug 2020 13:40:05

**US3022246**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 14:00:54

US3022246

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	24 Feb 2021 00:25:45
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).	System	24 Sep 2020 14:01:12
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 by data change (Site from System).		24 Sep 2020 14:01:12
User entered '28 Aug 2020' reason for change: Data Entry Error	Chevon Roberts (b) (4) (b) (4)	24 Sep 2020 14:01:12
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).	System	24 Sep 2020 14:00:54
User entered '04 Sep 2020'	Chevon Roberts (b) (4) (b) (4)	24 Sep 2020 14:00:54

**US3022246**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Chevon Roberts (b) (4)	24 Sep 2020 14:00:54
	(b) (4)	

**US3022246**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	24 Sep 2020 14:00:54
	(b) (4)	

US3022246

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	24 Sep 2020 14:01:16
	(b) (4)	

**US3022246**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'I'	(b) (4), (b) (6) System	24 Sep 2020 14:01:16



**US3022246**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 14:01:48

**US3022246**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '04 Sep 2020'	(b) (4) Chevon Roberts (b) (4) (b) (4)	24 Sep 2020 14:01:48

**US3022246**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 14:01:48

US3022246

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:46

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	24 Sep 2020 14:01:48
	(b) (4)	

US3022246

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 14:01:51

**US3022246**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'I'	(b) (4), (b) (6) System	24 Sep 2020 14:01:51

**US3022246**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 14:02:06

US3022246

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '14 Sep 2020'	(b) (4) Chevon Roberts (b) (4) (b) (4)	24 Sep 2020 14:02:06



**US3022246**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Chevon Roberts (b) (4)	24 Sep 2020 14:02:06
	(b) (4)	

**US3022246**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	24 Sep 2020 14:02:06
	(b) (4)	

**US3022246**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 14:02:13

**US3022246**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'I'	(b) (4), (b) (6) System	24 Sep 2020 14:02:13

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:27:10

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '24 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 18:27:10

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

[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 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:27:10

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'VISIT2'	(b) (4), (b) (6) System	01 Oct 2020 18:27:10



**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	01 Oct 2020 18:29:07

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:29:07

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '24 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 18:29:07

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '08:35'	(b) (4), (b) (6)	01 Oct 2020 18:29:07

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered '24 Sep 2020 08:35'	(b) (4), (b) (6) System	01 Oct 2020 18:29:07

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '36.8' C	(b) (4), (b) (6)	01 Oct 2020 18:29:07

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 18:29:07

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:29:07



**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '72'	(b) (4), (b) (6)	01 Oct 2020 18:29:07

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'bpm'	(b) (4), (b) (6) System	01 Oct 2020 18:29:07

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '14'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:29:07

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'breaths/min'	(b) (4), (b) (6) System	01 Oct 2020 18:29:07

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '136'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:29:07

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'mmHg'	(b) (4), (b) (6) System	01 Oct 2020 18:29:07

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '84'	(b) (4), (b) (6)	01 Oct 2020 18:29:07

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:50:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'mmHg'	(b) (4), (b) (6) System	01 Oct 2020 18:29:07



US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	01 Oct 2020 18:28:40

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:40

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:40

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '10:18'	(b) (4), (b) (6)	01 Oct 2020 18:28:40

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered '24 Sep 2020 10:18'	(b) (4), (b) (6) System	01 Oct 2020 18:28:40

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '36.8' C	(b) (4), (b) (6)	01 Oct 2020 18:28:40

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 18:28:40

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:50:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:28:40



US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '70'	(b) (4), (b) (6)	01 Oct 2020 18:28:40

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:50:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'bpm'	(b) (4), (b) (6) System	01 Oct 2020 18:28:40

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '14'	(b) (4), (b) (6)	01 Oct 2020 18:28:40

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'breaths/min'	(b) (4), (b) (6) System	01 Oct 2020 18:28:40

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '124'	(b) (4), (b) (6)	01 Oct 2020 18:28:40

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'mmHg'	(b) (4), (b) (6) System	01 Oct 2020 18:28:40

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '78'	(b) (4), (b) (6)	01 Oct 2020 18:28:40

US3022246

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:50:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'mmHg'	(b) (4), (b) (6) System	01 Oct 2020 18:28:40



US3022246

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:27:16

US3022246

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '24 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 18:27:16

US3022246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	24 Sep 2020 14:02:29
	(b) (4)	

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:50:46**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	24 Sep 2020 14:02:29
	(b) (4)	

US3022246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:46

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 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered empty.	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 14:02:29
	(b) (4)	

US3022246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '24 Sep 2020'	Chevon Roberts (b) (4)	24 Sep 2020 14:02:29
	(b) (4)	

US3022246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '09:46'	Chevon Roberts (b) (4)	24 Sep 2020 14:02:29
	(b) (4)	



US3022246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered '24 Sep 2020 09:46'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Chevon Roberts (b) (4)	24 Sep 2020 14:02:29
	(b) (4)	

US3022246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'ONCE'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:50:46

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:27:33

US3022246

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '24 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 18:27:33

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:46**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '08:55'	(b) (4), (b) (6)	01 Oct 2020 18:27:33

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered '24 Sep 2020 08:55'	(b) (4), (b) (6) System	01 Oct 2020 18:27:33



US3022246

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:50:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:27:46

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) (b) (4), (b) (6)	01 Oct 2020 18:27:46

US3022246

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:50:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:27:46

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '08:47'	(b) (4), (b) (6)	01 Oct 2020 18:27:46

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered '24 Sep 2020 08:47'	(b) (4), (b) (6) System	01 Oct 2020 18:27:46

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:50:46**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) (b) (4), (b) (6)	01 Oct 2020 18:27:46

US3022246

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:50:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:27:46

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:50:46**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:27:46



**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered empty.	(b) (4), (b) (6) System	01 Oct 2020 18:27:46

US3022246

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:27:51

**US3022246**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'I'	(b) (4), (b) (6) System	01 Oct 2020 18:27:51

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T10:19:42', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '986a00f4-80dc-4a51-8f40-6de09bc4b40c' User entered 'Yes (Y)'	(b) (4), (b) (6) System	24 Sep 2020 14:20:06
	System	24 Sep 2020 14:20:06

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T10:19:50', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '986a00f4-80dc-4a51-8f40-6de09bc4b40c' User entered '98.2'	(b) (4), (b) (6) System	24 Sep 2020 14:20:06
	System	24 Sep 2020 14:20:06

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T10:19:56', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '986a00f4-80dc-4a51-8f40-6de09bc4b40c' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 14:20:06
	System	24 Sep 2020 14:20:06

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T10:20:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '986a00f4-80dc-4a51-8f40-6de09bc4b40c' User entered '24 Sep 2020 10:20'	(b) (4), (b) (6) System	24 Sep 2020 14:20:06
	System	24 Sep 2020 14:20:06



US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '24 Sep 2020 10:06'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '24 Sep 2020 12:36'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T19:50:48', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'b97b6f41-5fc1-435d-86c4-13a86c0caa36' User entered 'Yes (Y)'	(b) (4), (b) (6) System	24 Sep 2020 23:51:06
	System	24 Sep 2020 23:51:06

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T19:50:55', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'b97b6f41-5fc1-435d-86c4-13a86c0caa36' User entered '98.3'	(b) (4), (b) (6) System	24 Sep 2020 23:51:06
	System	24 Sep 2020 23:51:06

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T19:50:59', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'b97b6f41-5fc1-435d-86c4-13a86c0caa36'	(b) (4), (b) (6)	
User entered 'No (N)'	System	24 Sep 2020 23:51:06

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T19:51:05', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'b97b6f41-5fc1-435d-86c4-13a86c0caa36' User entered '24 Sep 2020 19:51'	(b) (4), (b) (6) System	24 Sep 2020 23:51:06
	System	24 Sep 2020 23:51:06

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '24 Sep 2020 13:31'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29



US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '25 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 2'	System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-25T12:31:08', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8f2b5c61-2bc0-4c82-868e-2e79f0277ea9' User entered 'Yes (Y)'	(b) (4), (b) (6) System	25 Sep 2020 16:31:34
	System	25 Sep 2020 16:31:34

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-25T12:31:16', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8f2b5c61-2bc0-4c82-868e-2e79f0277ea9' User entered '100.5'	(b) (4), (b) (6) System	25 Sep 2020 16:31:34
	System	25 Sep 2020 16:31:34

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-25T12:31:20', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8f2b5c61-2bc0-4c82-868e-2e79f0277ea9'	(b) (4), (b) (6)	
	System	25 Sep 2020 16:31:34
User entered 'No (N)'	System	25 Sep 2020 16:31:34

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-25T12:31:30', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8f2b5c61-2bc0-4c82-868e-2e79f0277ea9' User entered '25 Sep 2020 12:31'	(b) (4), (b) (6) System	25 Sep 2020 16:31:34
	System	25 Sep 2020 16:31:34

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '25 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:50:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29



US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 3'	System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T04:57:29', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '28406464-32cc-4aaf-9bab-10a028cc5bfd' User entered 'Yes (Y)'	(b) (4), (b) (6) System	27 Sep 2020 08:57:49
	System	27 Sep 2020 08:57:49

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T04:57:37', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '28406464-32cc-4aaf-9bab-10a028cc5bfd' User entered '98.6'	(b) (4), (b) (6) System	27 Sep 2020 08:57:49
	System	27 Sep 2020 08:57:49

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T04:57:40', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '28406464-32cc-4aaf-9bab-10a028cc5bfd' User entered 'No (N)'	(b) (4), (b) (6) System	27 Sep 2020 08:57:49
	System	27 Sep 2020 08:57:49

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T04:57:44', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '28406464-32cc-4aaf-9bab-10a028cc5bfd' User entered '27 Sep 2020 04:57'	(b) (4), (b) (6) System	27 Sep 2020 08:57:49
	System	27 Sep 2020 08:57:49

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:50:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 4'	System	24 Sep 2020 14:02:29



US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T12:19:55', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '32b27aa5-580f-41db-a235-d7bf1d106ce7' User entered 'Yes (Y)'	(b) (4), (b) (6) System	27 Sep 2020 16:20:12
	System	27 Sep 2020 16:20:12

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T12:20:01', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '32b27aa5-580f-41db-a235-d7bf1d106ce7' User entered '98.5'	(b) (4), (b) (6) System	27 Sep 2020 16:20:12
	System	27 Sep 2020 16:20:12

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T12:20:04', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '32b27aa5-580f-41db-a235-d7bf1d106ce7' User entered 'No (N)'	(b) (4), (b) (6) System	27 Sep 2020 16:20:12
	System	27 Sep 2020 16:20:12

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T12:20:10', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '32b27aa5-580f-41db-a235-d7bf1d106ce7' User entered '27 Sep 2020 12:20'	(b) (4), (b) (6) System	27 Sep 2020 16:20:12
	System	27 Sep 2020 16:20:12

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:50:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 5'	System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-28T16:34:38', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '0c28b182-52db-4322-b1e8-fe76d2e53cc3' User entered 'Yes (Y)'	(b) (4), (b) (6) System	28 Sep 2020 20:34:56
	System	28 Sep 2020 20:34:56



US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-28T16:34:43', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '0c28b182-52db-4322-b1e8-fe76d2e53cc3' User entered '98.3'	(b) (4), (b) (6) System	28 Sep 2020 20:34:56
	System	28 Sep 2020 20:34:56

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-28T16:34:46', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '0c28b182-52db-4322-b1e8-fe76d2e53cc3'	(b) (4), (b) (6)	28 Sep 2020 20:34:56
User entered 'No (N)'	System	28 Sep 2020 20:34:56

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-28T16:34:49', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '0c28b182-52db-4322-b1e8-fe76d2e53cc3' User entered '28 Sep 2020 16:34'	(b) (4), (b) (6) System	28 Sep 2020 20:34:56
	System	28 Sep 2020 20:34:56

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 6'	System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-29T16:54:55', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'c4ffa01d-e721-4c1c-a819-a258262e5393' User entered 'Yes (Y)'	(b) (4), (b) (6) System	29 Sep 2020 20:55:09
	System	29 Sep 2020 20:55:09

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-29T16:55:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'c4ffa01d-e721-4c1c-a819-a258262e5393' User entered '98.5'	(b) (4), (b) (6) System	29 Sep 2020 20:55:09
	System	29 Sep 2020 20:55:09



US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-29T16:55:02', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'c4ffa01d-e721-4c1c-a819-a258262e5393'	(b) (4), (b) (6)	
	System	29 Sep 2020 20:55:09
User entered 'No (N)'	System	29 Sep 2020 20:55:09

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-29T16:55:07', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'c4ffa01d-e721-4c1c-a819-a258262e5393' User entered '29 Sep 2020 16:55'	(b) (4), (b) (6) System	29 Sep 2020 20:55:09
	System	29 Sep 2020 20:55:09

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 7'	System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-30T16:37:56', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '72121d5c-5237-44b3-9bde-0811ef5ff7ab' User entered 'Yes (Y)'	(b) (4), (b) (6) System	30 Sep 2020 20:38:11
	System	30 Sep 2020 20:38:11

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-30T16:38:03', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '72121d5c-5237-44b3-9bde-0811ef5ff7ab' User entered '98.5'	(b) (4), (b) (6) System	30 Sep 2020 20:38:11
	System	30 Sep 2020 20:38:11

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-30T16:38:05', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '72121d5c-5237-44b3-9bde-0811ef5ff7ab'	(b) (4), (b) (6)	30 Sep 2020 20:38:11
User entered 'No (N)'	System	30 Sep 2020 20:38:11



US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-30T16:38:08', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '72121d5c-5237-44b3-9bde-0811ef5ff7ab' User entered '30 Sep 2020 16:38'	(b) (4), (b) (6) System	30 Sep 2020 20:38:11
	System	30 Sep 2020 20:38:11

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:50:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T10:20:17', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'b757707e-678c-4bda-b185-84bc144e031e' User entered 'None (1)'	(b) (4), (b) (6) System	24 Sep 2020 14:20:56
	System	24 Sep 2020 14:20:56

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T10:20:26', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'b757707e-678c-4bda-b185-84bc144e031e' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 14:20:56
	System	24 Sep 2020 14:20:56

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T10:20:30', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'b757707e-678c-4bda-b185-84bc144e031e' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 14:20:56
	System	24 Sep 2020 14:20:56

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T10:20:35', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'b757707e-678c-4bda-b185-84bc144e031e' User entered 'None (1)'	(b) (4), (b) (6) System	24 Sep 2020 14:20:56
	System	24 Sep 2020 14:20:56



**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T10:20:53', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'b757707e-678c-4bda-b185-84bc144e031e' User entered '24 Sep 2020 10:20'	(b) (4), (b) (6) System	24 Sep 2020 14:20:56
	System	24 Sep 2020 14:20:56

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '24 Sep 2020 10:06'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '24 Sep 2020 12:36'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T19:51:12', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f147aca2-b052-4346-8b5e-fed6cae6554c' User entered 'None (1)'	(b) (4), (b) (6) System	24 Sep 2020 23:51:29
	System	24 Sep 2020 23:51:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T19:51:15', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f147aca2-b052-4346-8b5e-fed6cae6554c' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 23:51:29
	System	24 Sep 2020 23:51:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T19:51:19', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f147aca2-b052-4346-8b5e-fed6cae6554c' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 23:51:29
	System	24 Sep 2020 23:51:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T19:51:23', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f147aca2-b052-4346-8b5e-fed6cae6554c' User entered 'None (1)'	(b) (4), (b) (6) System	24 Sep 2020 23:51:29
	System	24 Sep 2020 23:51:29



**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T19:51:26', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f147aca2-b052-4346-8b5e-fed6cae6554c' User entered '24 Sep 2020 19:51'	(b) (4), (b) (6) System	24 Sep 2020 23:51:29
	System	24 Sep 2020 23:51:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '24 Sep 2020 13:31'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '25 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 2'	System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-25T12:31:41', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '6a99c0a1-a497-4dc9-825d-9ce25ac1686a' User entered 'Does not interfere with activity (2)'	(b) (4), (b) (6) System	25 Sep 2020 16:32:19
	System	25 Sep 2020 16:32:19

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-25T12:31:45', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '6a99c0a1-a497-4dc9-825d-9ce25ac1686a' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 16:32:19
	System	25 Sep 2020 16:32:19

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-25T12:31:58', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '6a99c0a1-a497-4dc9-825d-9ce25ac1686a' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 16:32:19
	System	25 Sep 2020 16:32:19

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-25T12:32:11', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '6a99c0a1-a497-4dc9-825d-9ce25ac1686a' User entered 'None (1)'	(b) (4), (b) (6) System	25 Sep 2020 16:32:19
	System	25 Sep 2020 16:32:19



US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:50:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-25T12:32:16', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '6a99c0a1-a497-4dc9-825d-9ce25ac1686a' User entered '25 Sep 2020 12:32'	(b) (4), (b) (6) System	25 Sep 2020 16:32:19
	System	25 Sep 2020 16:32:19

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '25 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 3'	System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T04:57:51', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f3798437-b9e6-47ee-b9db-fb243e558421' User entered 'None (1)'	(b) (4), (b) (6) System	27 Sep 2020 08:58:07
	System	27 Sep 2020 08:58:07

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T04:57:54', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f3798437-b9e6-47ee-b9db-fb243e558421' User entered 'No (N)'	(b) (4), (b) (6) System	27 Sep 2020 08:58:07
	System	27 Sep 2020 08:58:07

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T04:57:57', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f3798437-b9e6-47ee-b9db-fb243e558421' User entered 'No (N)'	(b) (4), (b) (6) System	27 Sep 2020 08:58:07
	System	27 Sep 2020 08:58:07

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T04:58:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f3798437-b9e6-47ee-b9db-fb243e558421' User entered 'None (1)'	(b) (4), (b) (6) System	27 Sep 2020 08:58:07
	System	27 Sep 2020 08:58:07



**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T04:58:03', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f3798437-b9e6-47ee-b9db-fb243e558421' User entered '27 Sep 2020 04:58'	(b) (4), (b) (6) System	27 Sep 2020 08:58:07
	System	27 Sep 2020 08:58:07

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:50:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 4'	System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T12:20:16', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'a21d8cfa-a261-45fc-8d2e-044952d733ba' User entered 'None (1)'	(b) (4), (b) (6) System	27 Sep 2020 16:20:35
	System	27 Sep 2020 16:20:35

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T12:20:19', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'a21d8cfa-a261-45fc-8d2e-044952d733ba' User entered 'No (N)'	(b) (4), (b) (6) System	27 Sep 2020 16:20:35
	System	27 Sep 2020 16:20:35

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T12:20:22', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'a21d8cfa-a261-45fc-8d2e-044952d733ba' User entered 'No (N)'	(b) (4), (b) (6) System	27 Sep 2020 16:20:35
	System	27 Sep 2020 16:20:35

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T12:20:27', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'a21d8cfa-a261-45fc-8d2e-044952d733ba' User entered 'None (1)'	(b) (4), (b) (6) System	27 Sep 2020 16:20:35
	System	27 Sep 2020 16:20:35



**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T12:20:30', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'a21d8cfa-a261-45fc-8d2e-044952d733ba' User entered '27 Sep 2020 12:20'	(b) (4), (b) (6) System	27 Sep 2020 16:20:35
	System	27 Sep 2020 16:20:35

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 5'	System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-28T16:35:12', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'd00efa0a-2e29-4cbe-98b7-4ef6a5f0b66c' User entered 'None (1)'	(b) (4), (b) (6) System	28 Sep 2020 20:35:20
	System	28 Sep 2020 20:35:20

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-28T16:34:58', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'd00efa0a-2e29-4cbe-98b7-4ef6a5f0b66c' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 20:35:20
	System	28 Sep 2020 20:35:20

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-28T16:35:01', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'd00efa0a-2e29-4cbe-98b7-4ef6a5f0b66c' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 20:35:20
	System	28 Sep 2020 20:35:20

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-28T16:35:05', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'd00efa0a-2e29-4cbe-98b7-4ef6a5f0b66c' User entered 'None (1)'	(b) (4), (b) (6) System	28 Sep 2020 20:35:20
	System	28 Sep 2020 20:35:20



**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-28T16:35:14', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'd00efa0a-2e29-4cbe-98b7-4ef6a5f0b66c' User entered '28 Sep 2020 16:35'	(b) (4), (b) (6) System	28 Sep 2020 20:35:20
	System	28 Sep 2020 20:35:20

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 6'	System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-29T16:55:11', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8fce1fd3-b62f-4ece-a5c7-909c6199b98d' User entered 'None (1)'	(b) (4), (b) (6) System	29 Sep 2020 20:55:24
	System	29 Sep 2020 20:55:24

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-29T16:55:15', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8fce1fd3-b62f-4ece-a5c7-909c6199b98d' User entered 'No (N)'	(b) (4), (b) (6) System	29 Sep 2020 20:55:24
	System	29 Sep 2020 20:55:24

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-29T16:55:17', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8fce1fd3-b62f-4ece-a5c7-909c6199b98d' User entered 'No (N)'	(b) (4), (b) (6) System	29 Sep 2020 20:55:24
	System	29 Sep 2020 20:55:24

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-29T16:55:19', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8fce1fd3-b62f-4ece-a5c7-909c6199b98d' User entered 'None (1)'	(b) (4), (b) (6) System	29 Sep 2020 20:55:24
	System	29 Sep 2020 20:55:24



**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-29T16:55:22', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8fce1fd3-b62f-4ece-a5c7-909c6199b98d' User entered '29 Sep 2020 16:55'	(b) (4), (b) (6) System	29 Sep 2020 20:55:24
	System	29 Sep 2020 20:55:24

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 7'	System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-30T16:38:13', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '3df6183d-49a8-4b4e-86cb-075f3df5eebe' User entered 'None (1)'	(b) (4), (b) (6) System	30 Sep 2020 20:38:26
	System	30 Sep 2020 20:38:26

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-30T16:38:16', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '3df6183d-49a8-4b4e-86cb-075f3df5eebe' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 20:38:26
	System	30 Sep 2020 20:38:26

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-30T16:38:17', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '3df6183d-49a8-4b4e-86cb-075f3df5eebe' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 20:38:26
	System	30 Sep 2020 20:38:26

US3022246

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:50:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-30T16:38:19', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '3df6183d-49a8-4b4e-86cb-075f3df5eebe'	(b) (4), (b) (6) System	30 Sep 2020 20:38:26
User entered 'None (1)'	System	30 Sep 2020 20:38:26



**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-30T16:38:22', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '3df6183d-49a8-4b4e-86cb-075f3df5eebe' User entered '30 Sep 2020 16:38'	(b) (4), (b) (6) System	30 Sep 2020 20:38:26
	System	30 Sep 2020 20:38:26

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T10:20:58', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'daa77b40-684e-4de2-a25f-18d011cbdcbl' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 14:21:20
	System	24 Sep 2020 14:21:20

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T10:21:01', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'daa77b40-684e-4de2-a25f-18d011cbdcbl' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 14:21:20
	System	24 Sep 2020 14:21:20

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T10:21:04', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'daa77b40-684e-4de2-a25f-18d011cbdcbl' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 14:21:20
	System	24 Sep 2020 14:21:20

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T10:21:06', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'daa77b40-684e-4de2-a25f-18d011cbdcbl' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 14:21:20
	System	24 Sep 2020 14:21:20



**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:46**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T10:21:08', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'daa77b40-684e-4de2-a25f-18d011cbdcbl' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 14:21:20
	System	24 Sep 2020 14:21:20

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T10:21:10', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'daa77b40-684e-4de2-a25f-18d011cbdcbl' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 14:21:20
	System	24 Sep 2020 14:21:20

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T10:21:13', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'daa77b40-684e-4de2-a25f-18d011cbdcbl' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 14:21:20
	System	24 Sep 2020 14:21:20

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T10:21:16', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'daa77b40-684e-4de2-a25f-18d011cbdcbl' User entered '24 Sep 2020 10:21'	(b) (4), (b) (6) System	24 Sep 2020 14:21:20
	System	24 Sep 2020 14:21:20

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '24 Sep 2020 10:06'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '24 Sep 2020 12:36'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T19:51:33', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '16e050a9-4ff2-44ba-b076-1c714bd98368' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 23:51:56
	System	24 Sep 2020 23:51:56



US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T19:51:36', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '16e050a9-4ff2-44ba-b076-1c714bd98368' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 23:51:56
	System	24 Sep 2020 23:51:56

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T19:51:38', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '16e050a9-4ff2-44ba-b076-1c714bd98368' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 23:51:56
	System	24 Sep 2020 23:51:56

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T19:51:41', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '16e050a9-4ff2-44ba-b076-1c714bd98368' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 23:51:56
	System	24 Sep 2020 23:51:56

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T19:51:43', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '16e050a9-4ff2-44ba-b076-1c714bd98368' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 23:51:56
	System	24 Sep 2020 23:51:56

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T19:51:47', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '16e050a9-4ff2-44ba-b076-1c714bd98368' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 23:51:56
	System	24 Sep 2020 23:51:56

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T19:51:50', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '16e050a9-4ff2-44ba-b076-1c714bd98368' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 23:51:56
	System	24 Sep 2020 23:51:56

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-24T19:51:54', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '16e050a9-4ff2-44ba-b076-1c714bd98368' User entered '24 Sep 2020 19:51'	(b) (4), (b) (6) System	24 Sep 2020 23:51:56
	System	24 Sep 2020 23:51:56

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '24 Sep 2020 13:31'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29



**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '25 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 2'	System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-25T12:32:39', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'cd84f8e1-528e-4475-b2da-cd77515828ce'	(b) (4), (b) (6)	
	System	25 Sep 2020 16:33:20
User entered 'No interference with activity (1)'	System	25 Sep 2020 16:33:20

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-25T12:32:45', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'cd84f8e1-528e-4475-b2da-cd77515828ce'	(b) (4), (b) (6)	
	System	25 Sep 2020 16:33:20
User entered 'No interference with activity (1)'	System	25 Sep 2020 16:33:20

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-25T12:32:54', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'cd84f8e1-528e-4475-b2da-cd77515828ce' User entered 'Some interference with activity (2)'	(b) (4), (b) (6) System	25 Sep 2020 16:33:20
	System	25 Sep 2020 16:33:20

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-25T12:32:59', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'cd84f8e1-528e-4475-b2da-cd77515828ce'	(b) (4), (b) (6)	
	System	25 Sep 2020 16:33:20
User entered 'Some interference with activity (2)'	System	25 Sep 2020 16:33:20

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-25T12:33:02', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'cd84f8e1-528e-4475-b2da-cd77515828ce' User entered 'None (0)'	(b) (4), (b) (6) System	25 Sep 2020 16:33:20
	System	25 Sep 2020 16:33:20

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:46

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-25T12:33:08', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'cd84f8e1-528e-4475-b2da-cd77515828ce'	(b) (4), (b) (6)	
	System	25 Sep 2020 16:33:20
User entered 'Some interference with activity not requiring medical attention (2)'	System	25 Sep 2020 16:33:20



US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-25T12:33:13', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'cd84f8e1-528e-4475-b2da-cd77515828ce' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 16:33:20
	System	25 Sep 2020 16:33:20

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-25T12:33:16', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'cd84f8e1-528e-4475-b2da-cd77515828ce' User entered '25 Sep 2020 12:33'	(b) (4), (b) (6) System	25 Sep 2020 16:33:20
	System	25 Sep 2020 16:33:20

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '25 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 3'	System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T04:58:08', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '05faf8b2-3a54-4df4-8e29-55e5b9eeba2d' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 08:58:28
	System	27 Sep 2020 08:58:28

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T04:58:11', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '05faf8b2-3a54-4df4-8e29-55e5b9eeba2d' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 08:58:28
	System	27 Sep 2020 08:58:28

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T04:58:13', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '05faf8b2-3a54-4df4-8e29-55e5b9eeba2d' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 08:58:28
	System	27 Sep 2020 08:58:28



US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T04:58:15', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '05faf8b2-3a54-4df4-8e29-55e5b9eeba2d' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 08:58:28
	System	27 Sep 2020 08:58:28

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T04:58:18', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '05faf8b2-3a54-4df4-8e29-55e5b9eeba2d' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 08:58:28
	System	27 Sep 2020 08:58:28

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T04:58:21', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '05faf8b2-3a54-4df4-8e29-55e5b9eeba2d' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 08:58:28
	System	27 Sep 2020 08:58:28

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T04:58:24', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '05faf8b2-3a54-4df4-8e29-55e5b9eeba2d' User entered 'No (N)'	(b) (4), (b) (6) System	27 Sep 2020 08:58:28
	System	27 Sep 2020 08:58:28

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T04:58:26', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '05faf8b2-3a54-4df4-8e29-55e5b9eeba2d' User entered '27 Sep 2020 04:58'	(b) (4), (b) (6) System	27 Sep 2020 08:58:28
	System	27 Sep 2020 08:58:28

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 4'	System	24 Sep 2020 14:02:29



US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T12:20:34', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '46f3f7da-2af4-4551-a122-3d4ca90ce178' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 16:20:54
	System	27 Sep 2020 16:20:54

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T12:20:36', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '46f3f7da-2af4-4551-a122-3d4ca90ce178' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 16:20:54
	System	27 Sep 2020 16:20:54

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T12:20:39', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '46f3f7da-2af4-4551-a122-3d4ca90ce178' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 16:20:54
	System	27 Sep 2020 16:20:54

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T12:20:41', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '46f3f7da-2af4-4551-a122-3d4ca90ce178' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 16:20:54
	System	27 Sep 2020 16:20:54

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T12:20:43', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '46f3f7da-2af4-4551-a122-3d4ca90ce178' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 16:20:54
	System	27 Sep 2020 16:20:54

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T12:20:46', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '46f3f7da-2af4-4551-a122-3d4ca90ce178' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 16:20:54
	System	27 Sep 2020 16:20:54

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T12:20:49', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '46f3f7da-2af4-4551-a122-3d4ca90ce178' User entered 'No (N)'	(b) (4), (b) (6) System	27 Sep 2020 16:20:54
	System	27 Sep 2020 16:20:54

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-27T12:20:52', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '46f3f7da-2af4-4551-a122-3d4ca90ce178' User entered '27 Sep 2020 12:20'	(b) (4), (b) (6) System	27 Sep 2020 16:20:54
	System	27 Sep 2020 16:20:54



**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 5'	System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-28T16:35:18', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '23524749-1709-4b58-92e6-c5bfd34fd93e' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 20:35:42
	System	28 Sep 2020 20:35:42

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-28T16:35:21', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '23524749-1709-4b58-92e6-c5bfd34fd93e' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 20:35:42
	System	28 Sep 2020 20:35:42

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-28T16:35:23', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '23524749-1709-4b58-92e6-c5bfd34fd93e' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 20:35:42
	System	28 Sep 2020 20:35:42

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-28T16:35:26', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '23524749-1709-4b58-92e6-c5bfd34fd93e' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 20:35:42
	System	28 Sep 2020 20:35:42

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-28T16:35:28', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '23524749-1709-4b58-92e6-c5bfd34fd93e' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 20:35:42
	System	28 Sep 2020 20:35:42



US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:46

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-28T16:35:30', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '23524749-1709-4b58-92e6-c5bfd34fd93e' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 20:35:42
	System	28 Sep 2020 20:35:42

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-28T16:35:34', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '23524749-1709-4b58-92e6-c5bfd34fd93e' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 20:35:42
	System	28 Sep 2020 20:35:42

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-28T16:35:40', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '23524749-1709-4b58-92e6-c5bfd34fd93e' User entered '28 Sep 2020 16:35'	(b) (4), (b) (6) System	28 Sep 2020 20:35:42
	System	28 Sep 2020 20:35:42

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 6'	System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-29T16:55:28', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '912d0a7c-a5cb-4371-8385-35f818f221c4' User entered 'None (0)'	(b) (4), (b) (6) System	29 Sep 2020 20:55:46
	System	29 Sep 2020 20:55:46

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-29T16:55:31', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '912d0a7c-a5cb-4371-8385-35f818f221c4' User entered 'None (0)'	(b) (4), (b) (6) System	29 Sep 2020 20:55:46
	System	29 Sep 2020 20:55:46



US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-29T16:55:32', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '912d0a7c-a5cb-4371-8385-35f818f221c4' User entered 'None (0)'	(b) (4), (b) (6) System	29 Sep 2020 20:55:46
	System	29 Sep 2020 20:55:46

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-29T16:55:35', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '912d0a7c-a5cb-4371-8385-35f818f221c4' User entered 'None (0)'	(b) (4), (b) (6) System	29 Sep 2020 20:55:46
	System	29 Sep 2020 20:55:46

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-29T16:55:37', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '912d0a7c-a5cb-4371-8385-35f818f221c4' User entered 'None (0)'	(b) (4), (b) (6) System	29 Sep 2020 20:55:46
	System	29 Sep 2020 20:55:46

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-29T16:55:39', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '912d0a7c-a5cb-4371-8385-35f818f221c4' User entered 'None (0)'	(b) (4), (b) (6) System	29 Sep 2020 20:55:46
	System	29 Sep 2020 20:55:46

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-29T16:55:42', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '912d0a7c-a5cb-4371-8385-35f818f221c4' User entered 'No (N)'	(b) (4), (b) (6) System	29 Sep 2020 20:55:46
	System	29 Sep 2020 20:55:46

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-29T16:55:45', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '912d0a7c-a5cb-4371-8385-35f818f221c4' User entered '29 Sep 2020 16:55'	(b) (4), (b) (6) System	29 Sep 2020 20:55:46
	System	29 Sep 2020 20:55:46

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29



US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 14:02:29
User entered 'Day 7'	System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:46**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-30T16:38:27', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'c69e284a-3a93-417e-8c72-0687e505d38d' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 20:38:48
	System	30 Sep 2020 20:38:48

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-30T16:38:29', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'c69e284a-3a93-417e-8c72-0687e505d38d' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 20:38:48
	System	30 Sep 2020 20:38:48

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-30T16:38:31', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'c69e284a-3a93-417e-8c72-0687e505d38d' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 20:38:48
	System	30 Sep 2020 20:38:48

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-30T16:38:32', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'c69e284a-3a93-417e-8c72-0687e505d38d' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 20:38:48
	System	30 Sep 2020 20:38:48

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:46

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-30T16:38:34', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'c69e284a-3a93-417e-8c72-0687e505d38d' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 20:38:48
	System	30 Sep 2020 20:38:48

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:46**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-30T16:38:36', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'c69e284a-3a93-417e-8c72-0687e505d38d' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 20:38:48
	System	30 Sep 2020 20:38:48

US3022246

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-30T16:38:39', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'c69e284a-3a93-417e-8c72-0687e505d38d' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 20:38:48
	System	30 Sep 2020 20:38:48



**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-09-30T16:38:42', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'c69e284a-3a93-417e-8c72-0687e505d38d' User entered '30 Sep 2020 16:38'	(b) (4), (b) (6) System	30 Sep 2020 20:38:48
	System	30 Sep 2020 20:38:48

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:50:46**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 14:02:29

**US3022246**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:02

**US3022246**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:02

**US3022246**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:02

US3022246

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:46

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:28:02

**US3022246**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:28:06



**US3022246**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'I'	(b) (4), (b) (6) System	01 Oct 2020 18:28:06

**US3022246**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 15:22:55

**US3022246**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '09 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 15:22:55

**US3022246**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 15:22:55

US3022246

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:46

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 15:22:55

**US3022246**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 15:23:01

**US3022246**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'I'	(b) (4), (b) (6) System	09 Oct 2020 15:23:01

**US3022246**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 16:19:13



**US3022246**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 16:19:13

**US3022246**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 16:19:13

US3022246

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:46

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:19:13

**US3022246**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 16:19:18

**US3022246**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'I'	(b) (4), (b) (6) System	20 Oct 2020 16:19:18

**US3022246**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:19:41

**US3022246**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 16:19:41

US3022246

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:50:46

[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 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 16:19:41



**US3022246**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'VISIT3'	(b) (4), (b) (6) System	20 Oct 2020 16:19:41

US3022246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:20:08

US3022246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '20 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 16:20:08

**US3022246**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '09:05'	(b) (4), (b) (6)	20 Oct 2020 16:20:08

**US3022246**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered '20 Oct 2020 09:05'	(b) (4), (b) (6) System	20 Oct 2020 16:20:08

US3022246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '36.6' C	(b) (4), (b) (6)	20 Oct 2020 16:20:08

US3022246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 16:20:08

**US3022246**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:20:08



**US3022246**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '72'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 16:20:08

**US3022246**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'bpm'	(b) (4), (b) (6) System	20 Oct 2020 16:20:08

US3022246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '16'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 16:20:08

US3022246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'breaths/min'	(b) (4), (b) (6) System	20 Oct 2020 16:20:08

**US3022246**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '138'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 16:20:08

US3022246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'mmHg'	(b) (4), (b) (6) System	20 Oct 2020 16:20:08

**US3022246**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '88'	(b) (4), (b) (6)	20 Oct 2020 16:20:08

US3022246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'mmHg'	(b) (4), (b) (6) System	20 Oct 2020 16:20:08



US3022246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	

US3022246

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	

US3022246

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:20:25

US3022246

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 16:20:25

US3022246

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:20:40

US3022246

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 16:20:40

**US3022246**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:46**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered '09:18'	(b) (4), (b) (6)	20 Oct 2020 16:20:40

**US3022246**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:46**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered '20 Oct 2020 09:18'	(b) (4), (b) (6) System	20 Oct 2020 16:20:40



US3022246

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:20:44

**US3022246**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'I'	(b) (4), (b) (6) System	20 Oct 2020 16:20:44

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 64'	System	21 Aug 2020 13:40:05

US3022246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-10-21T05:29:07', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f84c037f-b5cd-4f04-b38a-a4423e1bda56' User entered 'No (N)'	(b) (4), (b) (6) System	21 Oct 2020 09:29:23
	System	21 Oct 2020 09:29:23

US3022246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-10-21T05:29:15', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f84c037f-b5cd-4f04-b38a-a4423e1bda56'	(b) (4), (b) (6)	21 Oct 2020 09:29:23
User entered 'No (N)'	System	21 Oct 2020 09:29:23

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-10-21T05:29:19', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f84c037f-b5cd-4f04-b38a-a4423e1bda56' User entered '21 Oct 2020 05:29:19'	(b) (4), (b) (6) System	21 Oct 2020 09:29:23
	System	21 Oct 2020 09:29:23

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 13:40:05

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 13:40:05



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 71'	System	21 Aug 2020 13:40:05

US3022246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-10-30T12:45:13', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f9f64e48-b854-4739-b5f0-4e65ba19d07d' User entered 'No (N)'	(b) (4), (b) (6) System	30 Oct 2020 16:45:30
	System	30 Oct 2020 16:45:30

US3022246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-10-30T12:45:20', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f9f64e48-b854-4739-b5f0-4e65ba19d07d' User entered 'No (N)'	(b) (4), (b) (6) System	30 Oct 2020 16:45:30
	System	30 Oct 2020 16:45:30

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-10-30T12:45:24', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f9f64e48-b854-4739-b5f0-4e65ba19d07d' User entered '30 Oct 2020 12:45:24'	(b) (4), (b) (6) System	30 Oct 2020 16:45:30
	System	30 Oct 2020 16:45:30

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 13:40:05

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 13:40:05

US3022246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 78'	System	21 Aug 2020 13:40:05

US3022246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-11-06T12:00:54', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'b97d4ea9-2c4a-4679-9c59-bb87ddcd3ba2' User entered 'No (N)'	(b) (4), (b) (6) System	11 Nov 2020 16:14:37
	System	11 Nov 2020 16:14:37



US3022246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-11-06T12:01:08', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'b97d4ea9-2c4a-4679-9c59-bb87ddcd3ba2' User entered 'No (N)'	(b) (4), (b) (6) System	11 Nov 2020 16:14:37
	System	11 Nov 2020 16:14:37

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-11-06T12:01:16', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'b97d4ea9-2c4a-4679-9c59-bb87ddcd3ba2' User entered '06 Nov 2020 12:01:16'	(b) (4), (b) (6) System	11 Nov 2020 16:14:37
	System	11 Nov 2020 16:14:37

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 13:40:05

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 13:40:05

US3022246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered 'Day 92'	System	21 Aug 2020 13:40:05

US3022246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-11-18T07:01:25', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'd4d16a31-33f2-4128-87b9-4e703c803880' User entered 'No (N)'	(b) (4), (b) (6) System	18 Nov 2020 12:01:38
	System	18 Nov 2020 12:01:38

US3022246

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:50:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-11-18T07:01:29', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'd4d16a31-33f2-4128-87b9-4e703c803880' User entered 'No (N)'	(b) (4), (b) (6) System	18 Nov 2020 12:01:38
	System	18 Nov 2020 12:01:38

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-11-18T07:01:36', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'd4d16a31-33f2-4128-87b9-4e703c803880' User entered '18 Nov 2020 07:01:36'	(b) (4), (b) (6) System	18 Nov 2020 12:01:38
	System	18 Nov 2020 12:01:38



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 13:40:05

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:37
	(b) (4), (b) (6)	
Data entry locked.	System	21 Aug 2020 13:40:05
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 13:40:05

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-11-22T11:21:36', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'dfcd7d3e-3794-4d89-a8a3-22359d2a24d0'	System	22 Nov 2020 16:21:52
User entered 'No (N)'	System	22 Nov 2020 16:21:52

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-11-22T11:21:43', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'dfcd7d3e-3794-4d89-a8a3-22359d2a24d0'	System	22 Nov 2020 16:21:52
User entered 'No (N)'	System	22 Nov 2020 16:21:52

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-11-22T11:21:47', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'dfcd7d3e-3794-4d89-a8a3-22359d2a24d0' User entered '22 Nov 2020 11:21:47'	System	22 Nov 2020 16:21:52
	System	22 Nov 2020 16:21:52

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:23:29



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-12-03T09:56:41', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '44d8cbba-d6c0-4278-959b-9e8707e60991' User entered 'No (N)'	System	03 Dec 2020 14:56:52
	System	03 Dec 2020 14:56:52

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-12-03T09:56:45', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '44d8cbba-d6c0-4278-959b-9e8707e60991'	System	03 Dec 2020 14:56:52
User entered 'No (N)'	System	03 Dec 2020 14:56:52

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-12-03T09:56:49', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '44d8cbba-d6c0-4278-959b-9e8707e60991' User entered '03 Dec 2020 09:56:49'	System	03 Dec 2020 14:56:52
	System	03 Dec 2020 14:56:52

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-12-06T09:32:04', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '96edd985-6ea4-4df5-a65d-9595843cda38' User entered 'No (N)'	System	06 Dec 2020 14:32:18
	System	06 Dec 2020 14:32:18



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-12-06T09:32:11', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '96edd985-6ea4-4df5-a65d-9595843cda38' User entered 'No (N)'	System	06 Dec 2020 14:32:18
	System	06 Dec 2020 14:32:18

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-12-06T09:32:16', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '96edd985-6ea4-4df5-a65d-9595843cda38' User entered '06 Dec 2020 09:32:16'	System	06 Dec 2020 14:32:18
	System	06 Dec 2020 14:32:18

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-12-13T09:53:33', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8e9b446d-2119-4a32-9800-0df66a62c46d' User entered 'No (N)'	System	13 Dec 2020 14:53:47
	System	13 Dec 2020 14:53:47

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-12-13T09:53:40', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8e9b446d-2119-4a32-9800-0df66a62c46d' User entered 'No (N)'	System	13 Dec 2020 14:53:47
	System	13 Dec 2020 14:53:47

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-12-13T09:53:45', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8e9b446d-2119-4a32-9800-0df66a62c46d' User entered '13 Dec 2020 09:53:45'	System	13 Dec 2020 14:53:47
	System	13 Dec 2020 14:53:47



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-12-20T09:00:07', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '941d0a63-77c9-47a0-b953-9d92e763845e' User entered 'No (N)'	System	20 Dec 2020 14:00:29
	System	20 Dec 2020 14:00:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-12-20T09:00:21', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '941d0a63-77c9-47a0-b953-9d92e763845e' User entered 'No (N)'	System	20 Dec 2020 14:00:29
	System	20 Dec 2020 14:00:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-12-20T09:00:25', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '941d0a63-77c9-47a0-b953-9d92e763845e' User entered '20 Dec 2020 09:00:25'	System	20 Dec 2020 14:00:29
	System	20 Dec 2020 14:00:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 00:23:29



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-12-27T07:27:48', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '456150f2-dc7d-4a96-b351-5107bf384c90'	System	27 Dec 2020 12:28:09
User entered 'No (N)'	System	27 Dec 2020 12:28:09

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-12-27T07:27:56', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '456150f2-dc7d-4a96-b351-5107bf384c90'	System	27 Dec 2020 12:28:09
User entered 'No (N)'	System	27 Dec 2020 12:28:09

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2020-12-27T07:28:06', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '456150f2-dc7d-4a96-b351-5107bf384c90' User entered '27 Dec 2020 07:28:06'	System	27 Dec 2020 12:28:09
	System	27 Dec 2020 12:28:09

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-01-03T07:46:15', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '6094ddb1-15df-4985-9623-4730b13d748e' User entered 'No (N)'	System	03 Jan 2021 12:46:25
	System	03 Jan 2021 12:46:25



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-01-03T07:46:20', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '6094ddb1-15df-4985-9623-4730b13d748e'	System	03 Jan 2021 12:46:25
User entered 'No (N)'	System	03 Jan 2021 12:46:25

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-01-03T07:46:23', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '6094ddb1-15df-4985-9623-4730b13d748e' User entered '03 Jan 2021 07:46:23'	System	03 Jan 2021 12:46:25
	System	03 Jan 2021 12:46:25

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-01-10T13:03:05', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '3a32854a-4689-4c83-ae11-61fe77c47530' User entered 'No (N)'	System	10 Jan 2021 18:03:17
	System	10 Jan 2021 18:03:17

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-01-10T13:03:09', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '3a32854a-4689-4c83-ae11-61fe77c47530' User entered 'No (N)'	System	10 Jan 2021 18:03:17

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-01-10T13:03:14', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '3a32854a-4689-4c83-ae11-61fe77c47530' User entered '10 Jan 2021 13:03:14'	System	10 Jan 2021 18:03:17
	System	10 Jan 2021 18:03:17



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-01-17T05:55:55', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8fb45f26-d54e-4556-9f4c-ce6f4efd6a11' User entered 'No (N)'	System	17 Jan 2021 10:56:05

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-01-17T05:55:58', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8fb45f26-d54e-4556-9f4c-ce6f4efd6a11'	System	17 Jan 2021 10:56:05
User entered 'No (N)'	System	17 Jan 2021 10:56:05

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-01-17T05:56:01', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8fb45f26-d54e-4556-9f4c-ce6f4efd6a11' User entered '17 Jan 2021 05:56:01'	System	17 Jan 2021 10:56:05

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 00:23:29



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-01-24T09:19:03', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f89d50eb-951b-486f-b7ad-5e4ce1f76cd5'	System	24 Jan 2021 14:19:15
User entered 'No (N)'	System	24 Jan 2021 14:19:15

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-01-24T09:19:08', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f89d50eb-951b-486f-b7ad-5e4ce1f76cd5'	System	24 Jan 2021 14:19:15
User entered 'No (N)'	System	24 Jan 2021 14:19:15

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-01-24T09:19:11', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'f89d50eb-951b-486f-b7ad-5e4ce1f76cd5' User entered '24 Jan 2021 09:19:11'	System	24 Jan 2021 14:19:15
	System	24 Jan 2021 14:19:15

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-01-31T09:28:42', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'e7e89b2b-9ac2-4d61-977d-64d4f960aedic' User entered 'No (N)'	System	31 Jan 2021 14:28:55
	System	31 Jan 2021 14:28:55



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-01-31T09:28:46', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'e7e89b2b-9ac2-4d61-977d-64d4f960aedic' User entered 'No (N)'	System	31 Jan 2021 14:28:55
	System	31 Jan 2021 14:28:55

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-01-31T09:28:52', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'e7e89b2b-9ac2-4d61-977d-64d4f960aedic' User entered '31 Jan 2021 09:28:52'	System	31 Jan 2021 14:28:55
	System	31 Jan 2021 14:28:55

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-02-07T07:29:48', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '16ccb87b-fff5-40ee-865d-d0ddd1632ebc' User entered 'No (N)'	System	07 Feb 2021 12:29:58
	System	07 Feb 2021 12:29:58

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-02-07T07:29:52', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '16ccb87b-fff5-40ee-865d-d0ddd1632ebc' User entered 'No (N)'	System	07 Feb 2021 12:29:58

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-02-07T07:29:56', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '16ccb87b-fff5-40ee-865d-d0ddd1632ebc' User entered '07 Feb 2021 07:29:56'	System	07 Feb 2021 12:29:58
	System	07 Feb 2021 12:29:58



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-02-14T08:49:24', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '33effeb0-f7f5-443a-a0d1-7ff67a67d022'	System	14 Feb 2021 13:49:52
User entered 'No (N)'	System	14 Feb 2021 13:49:52

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-02-14T08:49:45', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '33effeb0-f7f5-443a-a0d1-7ff67a67d022'	System	14 Feb 2021 13:49:52
User entered 'No (N)'	System	14 Feb 2021 13:49:52

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-02-14T08:49:51', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '33effeb0-f7f5-443a-a0d1-7ff67a67d022' User entered '14 Feb 2021 08:49:51'	System	14 Feb 2021 13:49:52

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 00:23:29



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-02-21T09:07:51', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '1b48ac89-3596-4c43-9f76-79f71eb103ce' User entered 'No (N)'	System	21 Feb 2021 14:08:04
	System	21 Feb 2021 14:08:04

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-02-21T09:07:54', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '1b48ac89-3596-4c43-9f76-79f71eb103ce' User entered 'No (N)'	System	21 Feb 2021 14:08:04
	System	21 Feb 2021 14:08:04

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-02-21T09:08:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '1b48ac89-3596-4c43-9f76-79f71eb103ce' User entered '21 Feb 2021 09:08:00'	System	21 Feb 2021 14:08:04
	System	21 Feb 2021 14:08:04

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-02-28T09:08:23-05:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '7c76d2aa-a806-445a-84f9-6acccc3a2c9b' User entered 'No (N)'	System	28 Feb 2021 14:08:36
	System	28 Feb 2021 14:08:36



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-02-28T09:08:27-05:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '7c76d2aa-a806-445a-84f9-6acccc3a2c9b'	System	28 Feb 2021 14:08:36
User entered 'No (N)'	System	28 Feb 2021 14:08:36

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-02-28T09:08:32-05:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '7c76d2aa-a806-445a-84f9-6acccc3a2c9b'	System	28 Feb 2021 14:08:36
User entered '28 Feb 2021 14:08:32'	System	28 Feb 2021 14:08:36

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-03-07T09:08:45-05:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'a0fc0fe4-5bb5-47db-9516-48365d9e43cc'	System	07 Mar 2021 14:08:54
User entered 'No (N)'	System	07 Mar 2021 14:08:54

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-03-07T09:08:48-05:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'a0fc0fe4-5bb5-47db-9516-48365d9e43cc'	System	07 Mar 2021 14:08:54
User entered 'No (N)'	System	07 Mar 2021 14:08:54

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-03-07T09:08:52-05:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'a0fc0fe4-5bb5-47db-9516-48365d9e43cc'	System	07 Mar 2021 14:08:54
User entered '07 Mar 2021 09:08:52'	System	07 Mar 2021 14:08:54



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-03-14T08:10:37-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'b604ca2c-efee-4168-ab29-f0bd41e28ffc'	System	14 Mar 2021 12:10:52
User entered 'No (N)'	System	14 Mar 2021 12:10:52

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-03-14T08:10:43-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'b604ca2c-efee-4168-ab29-f0bd41e28ffc'	System	14 Mar 2021 12:10:52
User entered 'No (N)'	System	14 Mar 2021 12:10:52

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-03-14T08:10:46-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'b604ca2c-efee-4168-ab29-f0bd41e28ffc' User entered '14 Mar 2021 08:10:46'	System	14 Mar 2021 12:10:52
	System	14 Mar 2021 12:10:52

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 00:23:29



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-03-23T12:27:36-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'cb557600-f51e-433b-ba17-fa7ff7c22056'	System	23 Mar 2021 16:27:54
User entered 'No (N)'	System	23 Mar 2021 16:27:54

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-03-23T12:27:48-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'cb557600-f51e-433b-ba17-fa7ff7c22056'	System	23 Mar 2021 16:27:54
User entered 'No (N)'	System	23 Mar 2021 16:27:54

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-03-23T12:27:51-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'cb557600-f51e-433b-ba17-fa7ff7c22056'	System	23 Mar 2021 16:27:54
User entered '23 Mar 2021 12:27:51'	System	23 Mar 2021 16:27:54

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-03-28T10:06:48-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8fb62497-5a58-4ea4-8cb0-c9aed0e11130'	System	28 Mar 2021 14:06:56
User entered 'No (N)'	System	28 Mar 2021 14:06:56



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-03-28T10:06:51-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8fb62497-5a58-4ea4-8cb0-c9aed0e11130'	System	28 Mar 2021 14:06:56
User entered 'No (N)'	System	28 Mar 2021 14:06:56

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-03-28T10:06:54-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '8fb62497-5a58-4ea4-8cb0-c9aed0e11130'	System	28 Mar 2021 14:06:56
User entered '28 Mar 2021 10:06:54'	System	28 Mar 2021 14:06:56

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-04-04T09:03:52-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'db0cf8f5-056e-462c-909b-dd6cfcfb271d' User entered 'No (N)'	System	04 Apr 2021 13:04:05

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-04-04T09:03:57-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'db0cf8f5-056e-462c-909b-dd6cfcfb271d'	System	04 Apr 2021 13:04:05
User entered 'No (N)'	System	04 Apr 2021 13:04:05

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-04-04T09:04:01-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'db0cf8f5-056e-462c-909b-dd6cfcfb271d'	System	04 Apr 2021 13:04:05
User entered '04 Apr 2021 09:04:01'	System	04 Apr 2021 13:04:05



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-04-11T12:35:29-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'a22ec1e5-2cf0-49b0-9eed-3005f196c2d9'	System	11 Apr 2021 16:35:37
User entered 'No (N)'	System	11 Apr 2021 16:35:37

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-04-11T12:35:32-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'a22ec1e5-2cf0-49b0-9eed-3005f196c2d9'	System	11 Apr 2021 16:35:37
User entered 'No (N)'	System	11 Apr 2021 16:35:37

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-04-11T12:35:34-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'a22ec1e5-2cf0-49b0-9eed-3005f196c2d9'	System	11 Apr 2021 16:35:37
User entered '11 Apr 2021 12:35:34'	System	11 Apr 2021 16:35:37

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 00:23:29



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-04-18T08:07:42-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'fc9706cf-a81d-4661-84ee-963f63fdb0f3'	System	18 Apr 2021 12:07:51
User entered 'No (N)'	System	18 Apr 2021 12:07:51

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-04-18T08:07:45-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'fc9706cf-a81d-4661-84ee-963f63fdb0f3'	System	18 Apr 2021 12:07:51
User entered 'No (N)'	System	18 Apr 2021 12:07:51

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-04-18T08:07:48-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: 'fc9706cf-a81d-4661-84ee-963f63fdb0f3'	System	18 Apr 2021 12:07:51
User entered '18 Apr 2021 08:07:48'	System	18 Apr 2021 12:07:51

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-04-25T09:04:46-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '5b1965fa-a2ce-4e11-bd92-765a6dc67314' User entered 'No (N)'	System	25 Apr 2021 13:04:54
	System	25 Apr 2021 13:04:54



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-04-25T09:04:48-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '5b1965fa-a2ce-4e11-bd92-765a6dc67314'	System	25 Apr 2021 13:04:54
User entered 'No (N)'	System	25 Apr 2021 13:04:54

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-04-25T09:04:52-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '5b1965fa-a2ce-4e11-bd92-765a6dc67314' User entered '25 Apr 2021 09:04:52'	System	25 Apr 2021 13:04:54
	System	25 Apr 2021 13:04:54

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-05-02T07:37:20-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '385c8bee-de95-4345-ac31-dd920ef0d419'	System	02 May 2021 11:37:30
User entered 'No (N)'	System	02 May 2021 11:37:30

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

Have you been exposed to someone with 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 (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-05-02T07:37:23-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '385c8bee-de95-4345-ac31-dd920ef0d419'	System	02 May 2021 11:37:30
User entered 'No (N)'	System	02 May 2021 11:37:30

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-05-02T07:37:27-04:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '385c8bee-de95-4345-ac31-dd920ef0d419'	System	02 May 2021 11:37:30
User entered '02 May 2021 07:37:27'	System	02 May 2021 11:37:30



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 00:23:29



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 00:23:29



**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:23:29



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 00:23:29



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:23:29

**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 00:23:29



**US3022246**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:50:46**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:29
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 00:23:29

US3022246

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:50:46

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)	24 Apr 2021 11:54:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-02-28T09:08:41-05:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '2f9f903e-6f7c-4f91-b785-53fa2567c38e'	System	28 Feb 2021 14:08:50
User entered 'No (N)'	System	28 Feb 2021 14:08:50

**US3022246**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:54:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6AE0F84F-3218-4B92-A8B2-EE551D992515)', Time: '2021-02-28T09:08:46-05:00', User OID: 'PatientReportedOutcome (US3022246)', ODM File OID: '2f9f903e-6f7c-4f91-b785-53fa2567c38e' User entered '28 Feb 2021 14:08:46'	System	28 Feb 2021 14:08:50
	System	28 Feb 2021 14:08:50

**US3022246**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	08 Dec 2020 15:31:38

**US3022246**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '17 Nov 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	08 Dec 2020 15:31:38

**US3022246**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Shanice Bennett (b) (4)	08 Dec 2020 15:31:38

**US3022246**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered empty.	(b) (4) Shanice Bennett (b) (4)	08 Dec 2020 15:31:38

**US3022246**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4)	08 Dec 2020 15:31:46
	(b) (4)	



**US3022246**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:43:42
User entered 'I'	(b) (4), (b) (6) System	08 Dec 2020 15:31:46

**US3022246**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:01:08
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:03:46

**US3022246**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:01:08
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '22 Dec 2020'	(b) (4), (b) (6)	20 Jan 2021 20:03:46

**US3022246**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:01:08
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Jan 2021 20:03:46

**US3022246**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:01:08
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 20:03:46

**US3022246**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:01:08
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 20:03:50

**US3022246**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:01:08
User entered 'I'	System	20 Jan 2021 20:03:50

**US3022246**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:01:08
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 20:04:01



**US3022246**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:01:08
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '20 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 20:04:01

**US3022246**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:01:08
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Jan 2021 20:04:01

US3022246

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:50:46

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:01:08
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:04:01

**US3022246**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:01:08
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 20:04:06

**US3022246**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:01:08
User entered 'I'	System	20 Jan 2021 20:04:06

**US3022246**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:01:08
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Feb 2021 18:52:33

**US3022246**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:01:08
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '18 Feb 2021'	(b) (4), (b) (6)	18 Feb 2021 18:52:33

**US3022246**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:01:08
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Feb 2021 18:52:33



**US3022246**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:01:08
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 18:52:33

**US3022246**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:01:08
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:52:38

**US3022246**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:01:08
User entered '1'	System	18 Feb 2021 18:52:38

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 15:33:59

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:47
User entered '09 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 15:33:59

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:47
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:33:59

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User entered 'VISIT4'	System	09 Mar 2021 15:33:59

US3022246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:59:21



**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:53
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:59:21

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:53
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:59:21

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User entered empty.	System	30 Mar 2021 16:59:21

US3022246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:53
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:59:21

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:53
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:59:21

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:53
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:59:21

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:53
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:59:21

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User entered empty.	System	30 Mar 2021 16:59:21



US3022246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:53
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:59:21

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User entered empty.	System	30 Mar 2021 16:59:21

US3022246

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:50:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:53
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:59:21

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User entered empty.	System	30 Mar 2021 16:59:21

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:53
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:59:21

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User entered empty.	System	30 Mar 2021 16:59:21

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:50:46**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24



US3022246

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:50:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:34:07

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:50:46**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:47
User entered '09 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 15:34:07

US3022246

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 15:34:19

US3022246

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:50:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:47
User entered '09 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 15:34:19

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:46**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:47
User entered '09:43'	(b) (4), (b) (6)	09 Mar 2021 15:34:19

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User entered '09 Mar 2021 09:43'	System	09 Mar 2021 15:34:19

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 15:34:23

**US3022246**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:57:24
User entered 'I'	System	09 Mar 2021 15:34:23



**US3022246**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:19:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:38:23

**US3022246**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:19:52
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:38:23

**US3022246**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:19:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:38:23

**US3022246**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:50:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:19:52
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:38:23

US3022246

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:50:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:19:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:38:26

**US3022246**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:50:46**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 19:38:26

**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 13:11:57

**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 13:11:57



**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

[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 20:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 13:11:57

**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:50:46**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 13:11:57

**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:46**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 13:12:09

**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:46**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:47
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:25:38

**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:46**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 13:12:09

**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:46**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:47
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 13:25:38

**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:46**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 13:12:09

US3022246

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:50:46

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 13:12:09



**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:46**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 13:12:09

**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:46**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 13:12:09

**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:46**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 13:12:09

**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:46**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User entered empty.	System	28 Jan 2021 13:12:09

**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:50:46**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User entered empty.	System	28 Jan 2021 13:12:09

**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:46**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 13:12:24

**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:46**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 13:12:24

**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:46**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '14:27'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 13:12:24



**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:50:46**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User entered '27 Jan 2021 14:27'	System	28 Jan 2021 13:12:24

**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:50:46**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 13:12:32

**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:50:46**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 13:12:32

**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:50:46**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '14:44'	(b) (4), (b) (6)	28 Jan 2021 13:12:32

**US3022246**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:50:46**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:00:47
User entered '27 Jan 2021 14:44'	System	28 Jan 2021 13:12:32

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 14:50:46**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:58:04
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	18 Nov 2020 16:34:59

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:10:07
Reviewed for Safety.		19 Nov 2020 16:10:05
User entered 'USA-US051-2020-mRNA-1273-P301000011'	System	19 Nov 2020 16:09:16
User entered 'New'	(b) (4), (b) (6)	19 Nov 2020 16:09:16

US3022246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:46

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:33:45
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Jan 2021 19:03:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	13 Jan 2021 19:03:03
Data point term sent to Coder	System	13 Jan 2021 18:45:34
DataPoint Un-verified.	(b) (4), (b) (6)	13 Jan 2021 18:45:00
Coding entries removed.	(b) (4), (b) (6)	13 Jan 2021 18:45:00
User entered 'WORSENING OF LEFT HIP osteoarthritis' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 18:45:00
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 18:24:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	18 Nov 2020 18:24:51
Data point term sent to Coder	System	18 Nov 2020 16:37:19
User entered 'WORSENING OF LEFT HIP ARRHRITIS'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	



**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:37:00

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:37:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User closed query 'PV query: Please clarify start date of Left hip arthritis. SAE form states it started in 2010, whereas EDC has the start date in 2019.' (Site from Safety).		25 Nov 2020 19:43:33
Query 'PV query: Please clarify start date of Left hip arthritis. SAE form states it started in 2010, whereas EDC has the start date in 2019.' answered with 'updated mh' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:28:33
User opened query 'PV query: Please clarify start date of Left hip arthritis. SAE form states it started in 2010, whereas EDC has the start date in 2019.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 21:05:12
User entered '14 Nov 2020'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Nov 2020 16:37:36
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	18 Nov 2020 16:37:36
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Nov 2020 16:37:00
User entered '05:00'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:37:36
User entered '14 Nov 2020 05:00'	System	18 Nov 2020 16:37:00

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered 'No (N)'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered '15 Nov 2020'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:46

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	18 Nov 2020 16:37:36
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	18 Nov 2020 16:37:36
	(b) (4)	
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	18 Nov 2020 16:37:00
User entered '12:00'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:37:36
User entered '15 Nov 2020 12:00'	System	18 Nov 2020 16:37:00

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered 'Grade 4 (Grade 4)'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

US3022246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered '0'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered '0'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered 'I'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered '14 Nov 2020'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	



**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered '15 Nov 2020'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered 'No (N)'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered empty.	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered '0'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered '0'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered '0'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	



**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered 'Not Applicable (NOT APPLICABLE)'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered '0'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

US3022246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered 'I'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered 'I'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User entered empty.	Shanice Bennett (b) (4)	18 Nov 2020 16:37:00
	(b) (4)	

US3022246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:46

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
User closed query 'PV Query: Thank you for reaching out to the patient. Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 14:33:11
Query 'PV Query: Thank you for reaching out to the patient. Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. Please leave query open until information is available. ' answered with 'no covid test collected' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 13:13:29
User opened query 'PV Query: Thank you for reaching out to the patient. Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 14:19:58
User closed query 'PV Query: Thank you for reaching out to the patient. Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 20:12:00
Query 'PV Query: Thank you for reaching out to the patient. Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'still waiting on medical records' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 17:44:43
User opened query 'PV Query: Thank you for reaching out to the patient. Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 19:19:35

US3022246

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:50:46

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 15:10:07
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:43:28
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'I do not see hospital records in source will reach out to patient ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:31:18
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 21:05:28
User entered 'PRE-PLANNED SURGERY DUE TO WORSENING OF LEFT HIP ARTHRITIS.'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:37:00



**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 16:37:00

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 16:37:00

**US3022246**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Nov 2020 16:37:00

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:50:46

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:57:11
DataPoint Verified.		10 Dec 2020 14:37:12
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:47:21

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:58:57
DataPoint Verified.		10 Dec 2020 14:37:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 17:49:20
User coded data point as Term Coded data point by	(b) (4)	
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 17:48:08
User entered 'atorvastatin'	Stella Yoon (b) (4)	21 Aug 2020 17:48:01
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:57
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:01

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:57
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'hyperlipidemia'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:01

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:57
DataPoint Verified.		10 Dec 2020 14:37:48
User entered '10'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:01



US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:57
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'mg (mg)'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:01

US3022246

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:50:46**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4)	10 Dec 2020 15:58:57
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 17:48:01
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:57
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'once daily (QD)'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:01

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:57
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:01

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:57
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'Oral (ORAL)'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:01

US3022246

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:50:46**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4)	10 Dec 2020 15:58:57
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 17:48:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:57
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'un UNK 2010'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:01

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:57
DataPoint Verified.		10 Dec 2020 14:37:48
User entered '0'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:01



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4)	10 Dec 2020 15:58:57
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered 'Yes (Y)'	Stella Yoon (b) (4)	21 Aug 2020 17:48:01
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:57
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:01

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:50:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:57
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:01

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:48:01

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:48:01

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:50:46**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:48:01

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:58:59
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:37:48
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 03:50:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 03:50:39
Data point term sent to Coder	System	21 Aug 2020 17:49:10
User entered 'levothyroxine'	Stella Yoon (b) (4)	21 Aug 2020 17:48:24
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:59
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:24



US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:59
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'hypothyroidism'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:24

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:59
DataPoint Verified.		10 Dec 2020 14:37:48
User entered '88'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:24

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:59
DataPoint Verified.		10 Dec 2020 14:37:48
User closed query 'Per DM CLR-RQ: The response doesn't coincide with the query. Please review the UNIT as the dose is correct as per response but the UNIT may not be. Update as appropriate. Otherwise, provide clarification.' (Site from DM).		17 Nov 2020 09:46:35
Query 'Per DM CLR-RQ: The response doesn't coincide with the query. Please review the UNIT as the dose is correct as per response but the UNIT may not be. Update as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 19:28:11
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 19:27:54
User opened query 'Per DM CLR-RQ: The response doesn't coincide with the query. Please review the UNIT as the dose is correct as per response but the UNIT may not be. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 14:16:19
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).		20 Oct 2020 09:58:08
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'THIS DOSE IS CORRECT ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 21:11:50
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 08:58:20
User entered 'mg (mg)'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:24

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:59
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:24

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:59
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'once daily (QD)'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:24

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:59
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:24

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:59
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'Oral (ORAL)'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:24

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4)	10 Dec 2020 15:58:59
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered empty.	Stella Yoon (b) (4)	21 Aug 2020 17:48:24
	(b) (4)	



US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:59
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'un UNK 2015'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:24

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:59
DataPoint Verified.		10 Dec 2020 14:37:48
User entered '0'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:24

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:59
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:24

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:58:59
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	Stella Yoon (b) (4) (b) (4)	21 Aug 2020 17:48:24

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:50:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4)	10 Dec 2020 15:58:59
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered 'No (N)'	Stella Yoon (b) (4)	21 Aug 2020 17:48:24
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:50:46**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:48:24

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:50:46**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 17:48:24

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:50:46**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 17:48:24



US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:59:00
DataPoint Verified.		10 Dec 2020 14:37:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:42:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:42:43
Data point term sent to Coder	System	13 Nov 2020 19:30:05
User entered 'ibuprofen'	(b) (4), (b) (6)	13 Nov 2020 19:29:23

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:59:00
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 19:29:23

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:59:00
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'left hip osteoarthritis'	(b) (4), (b) (6)	13 Nov 2020 19:29:23

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4)	10 Dec 2020 15:59:00
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered '800'	(b) (4), (b) (6)	13 Nov 2020 19:29:23

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:50:46**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:59:00
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Nov 2020 19:29:23

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:59:00
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:29:23

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4)	10 Dec 2020 15:59:00
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered 'as needed (PRN)'	(b) (4), (b) (6)	13 Nov 2020 19:29:23

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:59:00
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:29:23



**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:50:46**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4)	10 Dec 2020 15:59:00
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Nov 2020 19:29:23

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:59:00
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:29:23

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4)	10 Dec 2020 15:59:00
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered 'un UNK 2019'	(b) (4), (b) (6)	13 Nov 2020 19:29:23

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:50:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4)	10 Dec 2020 15:59:00
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 19:29:23

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:50:46**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4)	10 Dec 2020 15:59:00
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 19:29:23

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:50:46**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4)	10 Dec 2020 15:59:00
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:29:23

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:50:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Un-verified.	(b) (4)	10 Dec 2020 15:59:00
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 19:29:23

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:50:46**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 19:29:23



**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:50:46**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 19:29:23

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:50:46**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 19:29:23

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:46

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:03
DataPoint Verified.		10 Dec 2020 14:37:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:47:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:47:56
Data point term sent to Coder	System	18 Nov 2020 16:39:22
User entered 'OXYCODONE ACETAMINOPHEN'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:39:11

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:46**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:03
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'No (N)'	Shanice Bennett (b) (4)	18 Nov 2020 16:39:11
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:03
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'WORSENING OF LEFT HIP ARTHRITIS'	Shanice Bennett (b) (4)	18 Nov 2020 16:39:11
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:46**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:03
DataPoint Verified.		10 Dec 2020 14:37:48
User entered '5/325'	Shanice Bennett (b) (4)	18 Nov 2020 16:39:11
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:46**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:03
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'mg (mg)'	Shanice Bennett (b) (4)	18 Nov 2020 16:39:11
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:03
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	Shanice Bennett (b) (4)	18 Nov 2020 16:39:11
	(b) (4)	



US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:03
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'as needed (PRN)'	Shanice Bennett (b) (4)	18 Nov 2020 16:39:11
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:03
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	Shanice Bennett (b) (4)	18 Nov 2020 16:39:11
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:03
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	18 Nov 2020 16:39:11
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:03
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	Shanice Bennett (b) (4)	18 Nov 2020 16:39:11
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:03
DataPoint Verified.		10 Dec 2020 14:37:48
User entered '14 Nov 2020'	Shanice Bennett (b) (4)	18 Nov 2020 16:39:11
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:03
DataPoint Verified.		10 Dec 2020 14:37:48
User entered '0'	Shanice Bennett (b) (4)	18 Nov 2020 16:39:11
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:03
DataPoint Verified.		10 Dec 2020 14:37:48
User closed query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. ' (Site from DM).		07 Dec 2020 06:37:46
Query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. ' answered with 'medicine still ongoing' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 13:33:50
User opened query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 01:27:40
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	18 Nov 2020 16:39:11
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:46**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:03
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	Shanice Bennett (b) (4)	18 Nov 2020 16:39:11
	(b) (4)	



US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:50:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:03
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'No (N)'	Shanice Bennett (b) (4)	18 Nov 2020 16:39:11
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:46**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:39:11

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:46**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:39:11

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:50:46**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:39:11

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:46

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:23:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:23:01
Data point term sent to Coder	System	31 Mar 2021 19:55:13
Coding entries removed.	(b) (4), (b) (6)	31 Mar 2021 19:54:45
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:10
DataPoint Un-verified.		10 Dec 2020 15:59:04
DataPoint Verified.		10 Dec 2020 14:37:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:02:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:02:58
Data point term sent to Coder	System	18 Nov 2020 16:40:24
User entered 'COLACE STOOL SOFTENER'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:40:09

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:50:46**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:10
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:04
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'No (N)'	Shanice Bennett (b) (4)	18 Nov 2020 16:40:09
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:21:53
DataPoint Un-verified.	(b) (4)	31 Mar 2021 19:54:45
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 19:54:45
User entered 'WORSENING OF LEFT osteoARTHRITIS' reason for change: Data Entry Error		31 Mar 2021 19:54:45
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:10
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:04
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'WORSENING OF LEFT HIP ARTHRITIS'	Shanice Bennett (b) (4)	18 Nov 2020 16:40:09
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:50:46**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:10
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:04
DataPoint Verified.		10 Dec 2020 14:37:48
User entered '100'	Shanice Bennett (b) (4)	18 Nov 2020 16:40:09
	(b) (4)	



**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:50:46**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:10
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:04
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'mg (mg)'	Shanice Bennett (b) (4)	18 Nov 2020 16:40:09
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:10
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:04
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	Shanice Bennett (b) (4)	18 Nov 2020 16:40:09
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:10
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:04
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'twice daily (BID)'	Shanice Bennett (b) (4)	18 Nov 2020 16:40:09
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:10
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:04
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	Shanice Bennett (b) (4)	18 Nov 2020 16:40:09
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:46

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:10
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:04
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	18 Nov 2020 16:40:09
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:50:46**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:10
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:04
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	Shanice Bennett (b) (4)	18 Nov 2020 16:40:09
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:10
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:04
DataPoint Verified.		10 Dec 2020 14:37:48
User entered '14 Nov 2020'	Shanice Bennett (b) (4)	18 Nov 2020 16:40:09
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:50:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:10
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:04
DataPoint Verified.		10 Dec 2020 14:37:48
User entered '0'	Shanice Bennett (b) (4)	18 Nov 2020 16:40:09
	(b) (4)	



US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:50:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:59:10
DataPoint Un-verified.		10 Dec 2020 15:59:04
DataPoint Verified.		10 Dec 2020 14:37:48
User closed query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. ' (Site from DM).		07 Dec 2020 06:38:16
Query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. ' answered with 'medication still ongoing' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 13:34:01
User opened query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 01:28:24
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:40:09

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:50:46**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:10
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:04
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	Shanice Bennett (b) (4)	18 Nov 2020 16:40:09
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:50:46**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 15:59:10
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:04
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'No (N)'	Shanice Bennett (b) (4)	18 Nov 2020 16:40:09
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:50:46**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Nov 2020 16:40:09

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:50:46**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 16:40:09

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:50:46**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 16:40:09

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:46

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 16:01:01
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:12
DataPoint Verified.		10 Dec 2020 14:37:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 16:57:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	18 Nov 2020 16:57:46
Data point term sent to Coder	System	18 Nov 2020 16:41:25
User entered 'ASPIRIN'	Shanice Bennett (b) (4)	18 Nov 2020 16:41:00
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:46**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 16:01:01
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:12
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	18 Nov 2020 16:41:00
	(b) (4)	



**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:46**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 16:01:01
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:12
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'CARDIAC PROPHYLAXIS'	Shanice Bennett (b) (4)	18 Nov 2020 16:41:00
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:46**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 16:01:01
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:12
DataPoint Verified.		10 Dec 2020 14:37:48
User entered '81'	Shanice Bennett (b) (4)	18 Nov 2020 16:41:00
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 16:01:01
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:12
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'mg (mg)'	Shanice Bennett (b) (4)	18 Nov 2020 16:41:00
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 16:01:01
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:12
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	Shanice Bennett (b) (4)	18 Nov 2020 16:41:00
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 16:01:01
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:12
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'twice daily (BID)'	Shanice Bennett (b) (4)	18 Nov 2020 16:41:00
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 16:01:01
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:12
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	Shanice Bennett (b) (4)	18 Nov 2020 16:41:00
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:46**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 16:01:01
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:12
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	18 Nov 2020 16:41:00
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 16:01:01
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:12
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	Shanice Bennett (b) (4)	18 Nov 2020 16:41:00
	(b) (4)	



US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 16:01:01
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:12
DataPoint Verified.		10 Dec 2020 14:37:48
User entered '14 Nov 2020'	Shanice Bennett (b) (4)	18 Nov 2020 16:41:00
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 16:01:01
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:12
DataPoint Verified.		10 Dec 2020 14:37:48
User entered '0'	Shanice Bennett (b) (4)	18 Nov 2020 16:41:00
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:47
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:35:43
Signature has been broken.	(b) (4), (b) (6)	09 Mar 2021 15:35:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 15:35:43
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:01:01
DataPoint Un-verified.		10 Dec 2020 15:59:12
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	18 Nov 2020 16:41:00
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:50:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:08:47
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:35:43
Signature has been broken.	(b) (4), (b) (6)	09 Mar 2021 15:35:43
User entered '20 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 15:35:43
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 16:01:01
DataPoint Un-verified.		10 Dec 2020 15:59:12
DataPoint Verified.		10 Dec 2020 14:37:48
User entered empty.	Shanice Bennett (b) (4)	18 Nov 2020 16:41:00
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:46**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	10 Dec 2020 16:01:01
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:59:12
DataPoint Verified.		10 Dec 2020 14:37:48
User entered 'No (N)'	Shanice Bennett (b) (4)	18 Nov 2020 16:41:00
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:46**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Nov 2020 16:41:00

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:46**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 16:41:00

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:50:46**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 16:41:00



US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:46

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: CARBAPENEMS, PRODUCT: CILASTATIN SODIUM;IMIPENEM, PRODUCTSYNONYM: PRIMAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Jan 2021 18:45:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Jan 2021 18:45:08
Data point term sent to Coder	System	13 Jan 2021 18:44:33
Coding entries removed.	(b) (4), (b) (6)	13 Jan 2021 18:43:57
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: CARBAPENEMS, PRODUCT: CILASTATIN SODIUM;IMIPENEM, PRODUCTSYNONYM: PRIMAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 16:43:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 16:43:46
Data point term sent to Coder	System	18 Nov 2020 16:42:29
User entered 'PRIMAXIN'	Shanice Bennett (b) (4)	18 Nov 2020 16:41:44

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:46**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered 'No (N)'	Shanice Bennett (b) (4)	18 Nov 2020 16:41:44
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 16:23:06
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 18:44:03
DataPoint Un-verified.	(b) (4), (b) (6)	13 Jan 2021 18:43:57
User entered 'WORSENING OF LEFT HIP osteoARTHRITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 18:43:57
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 05:44:44
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered 'WORSENING OF LEFT HIP ARTHRITIS'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:41:44

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:46

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
User closed query 'Per DM CLR: Please review the dose and route of administration recorded as this is not the standard dose and route for this medication. Also note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable. Please correct the dosage and route or provide explanation for alternate dosage and route. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Jan 2021 03:45:37
Query 'Per DM CLR: Please review the dose and route of administration recorded as this is not the standard dose and route for this medication. Also note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable. Please correct the dosage and route or provide explanation for alternate dosage and route. ' answered with 'this is correct per spurce and subject' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 18:44:33
User opened query 'Per DM CLR: Please review the dose and route of administration recorded as this is not the standard dose and route for this medication. Also note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable. Please correct the dosage and route or provide explanation for alternate dosage and route. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 05:45:17
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered '12.5'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:41:44

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:46

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered 'mg (mg)'	Shanice Bennett (b) (4)	18 Nov 2020 16:41:44
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:46

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered empty.	Shanice Bennett (b) (4)	18 Nov 2020 16:41:44
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:46

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered 'twice daily (BID)'	Shanice Bennett (b) (4)	18 Nov 2020 16:41:44
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered empty.	Shanice Bennett (b) (4)	18 Nov 2020 16:41:44
	(b) (4)	



US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:46

[Route of administration](#)

Audit	User	Time (GMT)
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) (6)	25 Feb 2021 18:08:03
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'this is correct' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 16:32:56
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)	04 Feb 2021 03:57:38
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	18 Nov 2020 16:41:44

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered empty.	Shanice Bennett (b) (4)	18 Nov 2020 16:41:44
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:46**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered '14 Nov 2020'	Shanice Bennett (b) (4)	18 Nov 2020 16:41:44
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:46**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered '0'	Shanice Bennett (b) (4)	18 Nov 2020 16:41:44
	(b) (4)	

US3022246

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:50:46

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:37:48
User closed query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 06:38:35
Query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. ' answered with 'medication still ongoing' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 13:34:22
User opened query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 01:28:37
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:41:44

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:46**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered empty.	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:41:44

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:46**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:37:48
User entered 'No (N)'	Shanice Bennett (b) (4)	18 Nov 2020 16:41:44
	(b) (4)	

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:46**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Nov 2020 16:41:44



**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:46**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 16:41:44

**US3022246**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:50:46**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 16:41:44

US3022246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:50:46

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:42
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:39:56
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	18 Nov 2020 16:42:02

US3022246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:50:46

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:57:26
User entered '14 Nov 2020'	Shanice Bennett (b) (4)	18 Nov 2020 16:42:23
	(b) (4)	

US3022246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:50:46

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:57:26
User entered 'LEFT HIP RELACEMENT'	Shanice Bennett (b) (4)	18 Nov 2020 16:42:23
	(b) (4)	

US3022246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:50:46

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:57:26
User entered 'Adverse Event (AE)'	Shanice Bennett (b) (4)	18 Nov 2020 16:42:23
	(b) (4)	

US3022246

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:50:46

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 15:57:26
User entered empty.	Shanice Bennett (b) (4)	18 Nov 2020 16:42:23
	(b) (4)	

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered	System	19 Nov 2020 16:09:16
'USA-US051-2020-MRNA-1273-P301000011'		



**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Yes (Y)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Yes (Y)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Paul'	System	19 Nov 2020 16:09:16



US3022246

Folder: SAE USA-US051-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 14:50:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Bradley'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered '340 Eisenhower Dr.'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Savannah'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'GA'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered '31406'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	27 Nov 2020 17:18:11
User entered 'US'	System	19 Nov 2020 16:12:04

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '3'	(b) (4)	14 Jan 2021 17:46:16
User entered '2'	System	25 Nov 2020 19:44:15
User entered '1'	System	19 Nov 2020 16:12:04

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered	System	19 Nov 2020 16:09:16
'USA-US051-2020-MRNA-1273-P301000011'		



**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Yes (Y)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Yes (Y)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Paul'	System	19 Nov 2020 16:09:16



**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Bradley'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered '340 Eisenhower Dr.'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Savannah'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'GA'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered '31406'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	27 Nov 2020 17:18:11
User entered 'US'	System	19 Nov 2020 16:12:04

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '3'	(b) (4)	14 Jan 2021 17:46:16
User entered '2'	System	25 Nov 2020 19:44:15
User entered '1'	System	19 Nov 2020 16:12:04

US3022246

Folder: SAE USA-US051-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:50:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:54:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:51:14
User entered '19/Nov/2020 16:12'	System	19 Nov 2020 16:12:04



US3022246

Folder: SAE USA-US051-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:50:46

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:54:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	27 Nov 2020 17:18:11
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 16:12:04

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered	System	19 Nov 2020 16:09:16
'USA-US051-2020-MRNA-1273-P301000011'		

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Yes (Y)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Yes (Y)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16



**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Paul'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Bradley'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered '340 Eisenhower Dr.'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Savannah'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'GA'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered '31406'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	27 Nov 2020 17:18:11
User entered 'US'	System	19 Nov 2020 16:12:04



**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '3'	(b) (4)	14 Jan 2021 17:46:16
User entered '2'	System	25 Nov 2020 19:44:15
User entered '1'	System	19 Nov 2020 16:12:04

US3022246

Folder: SAE USA-US051-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:50:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:54:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 14:53:21
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:51:14
User entered '25/Nov/2020 14:44'	System	25 Nov 2020 19:44:15

US3022246

Folder: SAE USA-US051-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:50:46

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:54:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 14:53:21
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	27 Nov 2020 17:18:11
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 19:44:15

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered	System	19 Nov 2020 16:09:16
'USA-US051-2020-MRNA-1273-P301000011'		

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Yes (Y)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Yes (Y)'	System	19 Nov 2020 16:09:16



**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'No (N)'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Paul'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Bradley'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered '340 Eisenhower Dr.'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'Savannah'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered 'GA'	System	19 Nov 2020 16:09:16



**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 16:10:40
User entered '31406'	System	19 Nov 2020 16:09:16

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:51:14
Reviewed for Safety.	(b) (4), (b) (6)	27 Nov 2020 17:18:11
User entered 'US'	System	19 Nov 2020 16:12:04

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:50:46**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '3'	(b) (4)	14 Jan 2021 17:46:16
User entered '2'	System	25 Nov 2020 19:44:15
User entered '1'	System	19 Nov 2020 16:12:04

**US3022246**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 14:50:46**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:54:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered '14/Jan/2021 12:46'	(b) (4) System	14 Jan 2021 17:46:16

US3022246

Folder: SAE USA-US051-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:50:46

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:54:08
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:25:45
User entered 'I'	(b) (4), (b) (6)	14 Jan 2021 17:46:16