

US3252624 (Prod: Centex Studies Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:14:24

All time stamps listed in this document are displayed in GMT

US3252624

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 22:17:03

Generated On: 09 Jun 2021 16:14:24

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[Participant ID](#)

US3252624

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

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US3252624

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 03:54:00

Generated On: 09 Jun 2021 16:14:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 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	SCRN

US3252624

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 03:53:32

Generated On: 09 Jun 2021 16:14:24

Date of Birth (MMM yyyy)	(b) (6) 1987
Age	33
Age Units	YEARS
Age (Derived)	33
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 03:54:00

Generated On: 09 Jun 2021 16:14:24

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

US3252624

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 03:54:00

Generated On: 09 Jun 2021 16:14:24

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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) 05 Mar 2021 03:54:00

Generated On: 09 Jun 2021 16:14:24

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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) 25 Mar 2021 19:38:40

Generated On: 09 Jun 2021 16:14:24

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 25 Mar 2021 19:38:40

Generated On: 09 Jun 2021 16:14:24

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	UN MAR 2016
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)	MAR 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3252624

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 03:54:00

Generated On: 09 Jun 2021 16:14:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	05 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	16:09 (24 HR)
Vital Signs Date and Time (derived)	05 OCT 2020 16:09
Height ( <i>xxx.x</i> )	66 in
Weight ( <i>xxx.x</i> )	328 lb
BMI ( <i>xxx.x</i> )	53.05128 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 03:54:00

Generated On: 09 Jun 2021 16:14:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 OCT 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 05 Mar 2021 03:53:32

Generated On: 09 Jun 2021 16:14:24

Date of assessment (*dd MMM yyyy*) 05 OCT 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

If Partner medically sterile or Other, specify \_\_\_\_\_  
If Surgically sterile, date of surgery (*dd MMM yyyy*) \_\_\_\_\_  
Date of surgery unknown False  
If Post-menopausal, date of last menstruation (*dd MMM yyyy*) \_\_\_\_\_  
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 05 Mar 2021 03:54:00

Generated On: 09 Jun 2021 16:14:24

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	5 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3252624

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 03:54:00

Generated On: 09 Jun 2021 16:14:24

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

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**Specify**

PET GROOMER

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 03:54:00

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 03:54:00

Generated On: 09 Jun 2021 16:14:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 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	VISIT1



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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Mar 2021 03:54:00

Generated On: 09 Jun 2021 16:14:24

What was the date of randomization? (dd MMM yyyy) 05 OCT 2020

What was the participant's randomization number? 146942

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) 05 Mar 2021 03:54:00

Generated On: 09 Jun 2021 16:14:24

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) 05 Mar 2021 03:54:00

Generated On: 09 Jun 2021 16:14:24

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)	05 OCT 2020
Time of assessment (00:00-23:59)	16:09 (24 HR)
Vital Signs Date and Time (derived)	05 OCT 2020 16:09
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 03:54:00

Generated On: 09 Jun 2021 16:14:24

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 OCT 2020
Time of assessment (00:00-23:59)	17:27 (24 HR)
Vital Signs Date and Time (derived)	05 OCT 2020 17:27
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 03:54:00

Generated On: 09 Jun 2021 16:14:24

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 05 Mar 2021 03:54:00

Generated On: 09 Jun 2021 16:14:24

Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (dd MMM yyyy) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 03:54:00

Generated On: 09 Jun 2021 16:14:24

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) 5 OCT 2020

What was the treatment time? (00:00-23:59) 16:57 (24 HR)

Treatment Date and Time (derived) 5 OCT 2020 16:57

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) 05 Mar 2021 03:54:00

Generated On: 09 Jun 2021 16:14:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	05 OCT 2020
Collection time ( <i>00:00-23:59</i> )	16:50 (24 HR)
Collection date and time (derived)	05 OCT 2020 16:50



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 03:54:00

Generated On: 09 Jun 2021 16:14:24

Collection date (dd MMM yyyy)			05 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:43	05 OCT 2020 16:43
Nasopharyngeal Swab 2	No		

US3252624

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:54:00

Generated On: 09 Jun 2021 16:14:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**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

98.0 °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

05 OCT 2020 17:27

PC Open Date & Time

05 OCT 2020 17:17

PC Close Date & Time

05 OCT 2020 19:47

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**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 97.3 °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	05 OCT 2020 23:40
PC Open Date & Time	05 OCT 2020 20:42
PC Close Date & Time	06 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False
PC Time Stamp	06 OCT 2020 20:26
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**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

98.7 °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

07 OCT 2020 19:28

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 23:11

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59



US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 22:12

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 23:45

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 17:27

PC Open Date & Time

05 OCT 2020 17:17

PC Close Date & Time

05 OCT 2020 19:47

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**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 ☐

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

1

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

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

Yes ☒

No ☐

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

1

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 23:42

PC Open Date & Time

05 OCT 2020 20:42

PC Close Date & Time

06 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

40

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

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

Yes ☒

No ☐

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

20

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 20:26

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**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 ☐

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

46

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

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

Yes ☒

No ☐

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

30

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 19:28

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**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 ☐

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

43

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

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

Yes ☒

No ☐

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

30

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 23:12

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59



US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**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

10 OCT 2020 22:13

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**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

11 OCT 2020 23:45

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**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 ☐

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

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

No ☒

Yes ☐

PC Time stamp	05 OCT 2020 17:28
PC Open Date & Time	05 OCT 2020 17:17
PC Close Date & Time	05 OCT 2020 19:47

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**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 ☐

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

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

No ☒

Yes ☐

PC Time stamp	05 OCT 2020 23:43
PC Open Date & Time	05 OCT 2020 20:42
PC Close Date & Time	06 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**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 ☒

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 20:19
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59



US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**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

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EAB) (1725)

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 19:29
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

50 of 1866

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 23:12
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**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 ☐

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

Yes ☐

PC Time stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

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 ☒

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 22:13
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59



US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**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 ☒

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 23:44
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 12 OCT 2020 23:59

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 13 OCT 2020 23:59

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 8

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

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 12 OCT 2020 23:59

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 16:14:24

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**TIMEPOINT**

DAY 9

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

None ☒

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

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PC Time stamp	13 OCT 2020 23:59
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PC Open Date & Time	13 OCT 2020 12:00
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PC Close Date & Time	14 OCT 2020 11:59
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US3252624

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 8

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

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 12 OCT 2020 23:59

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 16:14:24

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**TIMEPOINT**

DAY 9

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

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

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PC Time stamp 13 OCT 2020 23:59

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

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US3252624

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:14:24

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 OCT 2020 23:59
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3252624

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:14:24

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 OCT 2020 23:59
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3252624

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 03:53:32

Generated On: 09 Jun 2021 16:14:24

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3252624

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:53:32

Generated On: 09 Jun 2021 16:14:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252624

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 03:53:32

Generated On: 09 Jun 2021 16:14:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3252624

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:53:32

Generated On: 09 Jun 2021 16:14:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252624

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 03:53:32

Generated On: 09 Jun 2021 16:14:24

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3252624

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:53:32

Generated On: 09 Jun 2021 16:14:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3252624

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 03:54:01

Generated On: 09 Jun 2021 16:14:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 03:54:01

Generated On: 09 Jun 2021 16:14:24

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)	4 NOV 2020
Time of assessment (00:00-23:59)	09:22 (24 HR)
Vital Signs Date and Time (derived)	4 NOV 2020 09:22
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 03:54:01

Generated On: 09 Jun 2021 16:14:24

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 NOV 2020
Time of assessment (00:00-23:59)	10:53 (24 HR)
Vital Signs Date and Time (derived)	4 NOV 2020 10:53
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3252624

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 03:54:01

Generated On: 09 Jun 2021 16:14:24

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3252624

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 05 Mar 2021 03:54:01

Generated On: 09 Jun 2021 16:14:24

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	4 NOV 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 03:54:01

Generated On: 09 Jun 2021 16:14:24

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) 4 NOV 2020

What was the treatment time? (00:00-23:59) 10:23 (24 HR)

Treatment Date and Time (derived) 4 NOV 2020 10:23

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

US3252624

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 03:54:01

Generated On: 09 Jun 2021 16:14:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	4 NOV 2020
Collection time ( <i>00:00-23:59</i> )	10:12 (24 HR)
Collection date and time (derived)	4 NOV 2020 10:12

US3252624

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 03:54:01

Generated On: 09 Jun 2021 16:14:24

Collection date (dd MMM yyyy)			4 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:04	4 NOV 2020 10:04
Nasopharyngeal Swab 2	No		



US3252624

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:54:01

Generated On: 09 Jun 2021 16:14:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**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 98.3 °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):

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

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

PC Time Stamp 04 NOV 2020 10:54

PC Open Date & Time 04 NOV 2020 10:43

PC Close Date & Time 04 NOV 2020 13:13

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**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 97.3 °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):

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

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

PC Time Stamp 04 NOV 2020 22:23

PC Open Date & Time 04 NOV 2020 14:08

PC Close Date & Time 05 NOV 2020 11:59

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 NOV 2020 21:53

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**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

96.0 °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

06 NOV 2020 22:54

PC Open Date & Time

06 NOV 2020 12:00

PC Close Date & Time

07 NOV 2020 11:59

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 NOV 2020 20:56

PC Open Date & Time

07 NOV 2020 12:00

PC Close Date & Time

08 NOV 2020 11:59

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:14:24

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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

95.1 °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

08 NOV 2020 23:56

PC Open Date & Time

08 NOV 2020 12:00

PC Close Date & Time

09 NOV 2020 11:59

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**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

09 NOV 2020 21:06

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59



US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

11 NOV 2020 07:41

PC Open Date & Time

10 NOV 2020 12:00

PC Close Date & Time

11 NOV 2020 11:59

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**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

04 NOV 2020 10:55

PC Open Date & Time

04 NOV 2020 10:43

PC Close Date & Time

04 NOV 2020 13:13

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**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 ☐

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

20

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

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

Yes ☒

No ☐

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

20

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 NOV 2020 22:29

PC Open Date & Time

04 NOV 2020 14:08

PC Close Date & Time

05 NOV 2020 11:59

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☒

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

Yes ☒

No ☐

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

40

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

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

Yes ☒

No ☐

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

40

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 NOV 2020 21:55

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**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 ☐

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

40

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

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

Yes ☒

No ☐

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

40

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 NOV 2020 22:56

PC Open Date & Time

06 NOV 2020 12:00

PC Close Date & Time

07 NOV 2020 11:59

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

20

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 NOV 2020 20:57

PC Open Date & Time

07 NOV 2020 12:00

PC Close Date & Time

08 NOV 2020 11:59

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**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

08 NOV 2020 23:56

PC Open Date & Time

08 NOV 2020 12:00

PC Close Date & Time

09 NOV 2020 11:59

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**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

09 NOV 2020 21:05

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59



US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**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

11 NOV 2020 07:41

PC Open Date & Time

10 NOV 2020 12:00

PC Close Date & Time

11 NOV 2020 11:59

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**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 ☐

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

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

No ☒

Yes ☐

PC Time stamp	04 NOV 2020 10:55
PC Open Date & Time	04 NOV 2020 10:43
PC Close Date & Time	04 NOV 2020 13:13

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**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 ☐

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

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

No ☒

Yes ☐

PC Time stamp	04 NOV 2020 22:29
PC Open Date & Time	04 NOV 2020 14:08
PC Close Date & Time	05 NOV 2020 11:59

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**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 ☒

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

Yes <input type="checkbox"/>	
PC Time stamp	05 NOV 2020 21:55
PC Open Date & Time	05 NOV 2020 12:00
PC Close Date & Time	06 NOV 2020 11:59

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

Yes <input type="checkbox"/>	
PC Time stamp	06 NOV 2020 22:56
PC Open Date & Time	06 NOV 2020 12:00
PC Close Date & Time	07 NOV 2020 11:59

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**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 ☒

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

Yes <input type="checkbox"/>	
PC Time stamp	07 NOV 2020 20:56
PC Open Date & Time	07 NOV 2020 12:00
PC Close Date & Time	08 NOV 2020 11:59

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**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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EAB) (1725)

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US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

Yes <input type="checkbox"/>	
PC Time stamp	08 NOV 2020 23:56
PC Open Date & Time	08 NOV 2020 12:00
PC Close Date & Time	09 NOV 2020 11:59

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

Yes <input type="checkbox"/>	
PC Time stamp	09 NOV 2020 21:05
PC Open Date & Time	09 NOV 2020 12:00
PC Close Date & Time	10 NOV 2020 11:59

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

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 ☒

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US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

Yes <input type="checkbox"/>	
PC Time stamp	11 NOV 2020 07:41
PC Open Date & Time	10 NOV 2020 12:00
PC Close Date & Time	11 NOV 2020 11:59

US3252624

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 03:53:32

Generated On: 09 Jun 2021 16:14:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 NOV 2020

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

Comments LEFT VOICE MAIL

*If Contact Not Made, please provide Comments*

US3252624

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:53:32

Generated On: 09 Jun 2021 16:14:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252624

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 03:53:32

Generated On: 09 Jun 2021 16:14:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3252624

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:53:32

Generated On: 09 Jun 2021 16:14:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252624

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 03:53:32

Generated On: 09 Jun 2021 16:14:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3252624

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:53:32

Generated On: 09 Jun 2021 16:14:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252624

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 03:54:01

Generated On: 09 Jun 2021 16:14:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 DEC 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



US3252624

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 03:54:01

Generated On: 09 Jun 2021 16:14:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	2 DEC 2020
Time of assessment ( <i>00:00-23:59</i> )	09:49 (24 HR)
Vital Signs Date and Time (derived)	2 DEC 2020 09:49
Temperature ( <i>xxx.x</i> )	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	80 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252624

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 03:54:01

Generated On: 09 Jun 2021 16:14:24

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3252624

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 03:54:01

Generated On: 09 Jun 2021 16:14:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 DEC 2020
Collection time (00:00-23:59)	10:11 (24 HR)
Collection date and time (derived)	2 DEC 2020 10:11

US3252624

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 03:54:01

Generated On: 09 Jun 2021 16:14:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 16:19:12
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 68
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	09 DEC 2020 00:18:42
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 DEC 2020 07:45:53
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	23 DEC 2020 08:20:17
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59



US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 DEC 2020 05:16:35
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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	08 JAN 2021 23:08:07
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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

13 JAN 2021 01:23:28

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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

20 JAN 2021 18:47:43

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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

29 JAN 2021 12:41:45

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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

07 FEB 2021 11:59:26

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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

10 FEB 2021 00:02:26

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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

18 FEB 2021 18:22:41

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59



US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 FEB 2021 06:07:40
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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

03 MAR 2021 06:50:46

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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

10 MAR 2021 22:05:20

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 MAR 2021 06:35:01
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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

24 MAR 2021 21:22:01

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 12:35:13

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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

07 APR 2021 12:40:07

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	14 APR 2021 00:13:25
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59



US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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

21 APR 2021 07:19:35

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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

02 MAY 2021 12:20:15

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2021 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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16 MAY 2021 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Open Date & Time](#)

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09 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUN 2021 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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



US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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04 JUL 2021 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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11 JUL 2021 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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



US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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01 AUG 2021 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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08 AUG 2021 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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 <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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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15 AUG 2021 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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="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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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22 AUG 2021 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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 <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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	29 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 OCT 2021 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	06 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2021 23:59



US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	20 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59
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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	27 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2021 23:59
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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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07 NOV 2021 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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21 NOV 2021 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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="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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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



US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	29 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 JAN 2022 23:59



US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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05 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JAN 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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30 JAN 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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 <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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	02 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 FEB 2022 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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 <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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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



US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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 <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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Open Date & Time](#)

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09 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAR 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	06 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 APR 2022 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	13 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 APR 2022 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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24 APR 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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01 MAY 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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05 JUN 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

15 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUN 2022 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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03 JUL 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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17 JUL 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUL 2022 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JUL 2022 23:59

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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



US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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28 AUG 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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04 SEP 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59



US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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14 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 SEP 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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02 OCT 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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05 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 OCT 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	12 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59
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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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06 NOV 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Open Date & Time](#)

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09 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 NOV 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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°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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

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[Patient Cloud Close Date & Time](#)

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27 NOV 2022 23:59

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US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

**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 ☐

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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



US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 DEC 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 DEC 2022 23:59

US3252624

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:14:24

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		03 MAR 2021 06:51:00

US3252624

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:17:03

Generated On: 09 Jun 2021 16:14:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3252624

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:17:03

Generated On: 09 Jun 2021 16:14:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252624

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:17:03

Generated On: 09 Jun 2021 16:14:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3252624

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:17:03

Generated On: 09 Jun 2021 16:14:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252624

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:17:03

Generated On: 09 Jun 2021 16:14:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*



US3252624

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:17:03

Generated On: 09 Jun 2021 16:14:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252624

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:04:34

Generated On: 09 Jun 2021 16:14:24

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3252624

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:04:34

Generated On: 09 Jun 2021 16:14:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3252624**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:14:24**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3252624

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3252624

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:24

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

**US3252624**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:14:24**

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00-23:59</i> )	<hr/>
Collection date and time (derived)	<hr/>

**US3252624**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:14:24**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3252624

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:14:24

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"/>

**US3252624**

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

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

**Generated On: 09 Jun 2021 16:14:24**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3252624

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:04:34

Generated On: 09 Jun 2021 16:14:24

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

Visit date (dd MMM yyyy)	17 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	UNBLND_DECIDE
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US3252624

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 21:04:34

Generated On: 09 Jun 2021 16:14:24

Date of updated informed consent (*dd MMM yyyy*) 17 MAR 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*) 17 MAR 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 \_\_\_\_\_

US3252624

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:04:34

Generated On: 09 Jun 2021 16:14:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 MAR 2021
Collection time (00:00-23:59)	13:56 (24 HR)
Collection date and time (derived)	17 MAR 2021 13:56

US3252624

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 21:04:34

Generated On: 09 Jun 2021 16:14:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 MAR 2021
Collection time (00:00 - 23:59)	13:56
Collection Date and Time (derived)	17 MAR 2021 13:56

US3252624

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 11:51:32

Generated On: 09 Jun 2021 16:14:24

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3252624

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

AEID	USA-US108-2021-MRNA-1273-P30 1000021
Adverse event	BACTERIAL PNEUMONIA
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)	12 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 APR 2020
Hospital Discharge Date (dd MMM yyyy)	17 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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US3252624

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

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

US3252624

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:24

AEID

Adverse event

JOINT ACHES IN SEVERAL  
JOINTS

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

10 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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US3252624

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:24

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

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

AEID

Adverse event

MUSCLE ACHES ALL OVER  
BODY

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

10 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

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

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 22:17:03

Generated On: 09 Jun 2021 16:14:24

---

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

Yes ☒

No ☐

---

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

---

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 11:51:32

Generated On: 09 Jun 2021 16:14:24

Name of Medication VALSARTAN /  
HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 160/25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 11:51:32

Generated On: 09 Jun 2021 16:14:24

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2016	
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"/>



US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 11:51:32

Generated On: 09 Jun 2021 16:14:24

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication ARM PAIN

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 11:51:32

Generated On: 09 Jun 2021 16:14:24

	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)		6 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 6 OCT 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 11:51:32

Generated On: 09 Jun 2021 16:14:24

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication ARM PAIN

Dose per administration 400

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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US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 11:51:32

Generated On: 09 Jun 2021 16:14:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		4 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)		4 NOV 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 11:51:32

Generated On: 09 Jun 2021 16:14:24

Name of Medication	TRULICITY
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DIABETES TYPE 2
Dose per administration	1.5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input checked="" type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 11:51:32

Generated On: 09 Jun 2021 16:14:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 11:51:32

Generated On: 09 Jun 2021 16:14:24

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication DIABETES TYPE 2

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 11:51:32

Generated On: 09 Jun 2021 16:14:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 11:51:32

Generated On: 09 Jun 2021 16:14:24

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐  
No ☒

Indication BACTERIAL PNEUMONIA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 11:51:32

Generated On: 09 Jun 2021 16:14:24

	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)	17 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252624

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 22:17:03

Generated On: 09 Jun 2021 16:14:24

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3252624

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:14:24

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

US3252624

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:14:24

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 ☐

US3252624

Folder: SAE USA-US108-2021-MRNA-1273-P301000021

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 11:51:32

Generated On: 09 Jun 2021 16:14:24

SAEID	USA-US108-2021-MRNA-1273-P301000021
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	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3252624

Folder: SAE USA-US108-2021-MRNA-1273-P301000021

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 11:51:32

Generated On: 09 Jun 2021 16:14:24

SAEID	USA-US108-2021-MRNA-1273-P301000021
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	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/APR/2021 14:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3252624 (Prod: Centex Studies Inc)



**US3252624**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:14:24**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:17:03
User entered 'US3252624'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Oct 2020 21:22:47

**US3252624**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:14:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 21:35:57

US3252624

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '05 OCT 2020'	RWS_ENDPOINT	05 Oct 2020 21:22:49
	ENDPOINT (b) (4)	

US3252624

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:14:24

[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 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Oct 2020 21:35:57

**US3252624**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:14:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered 'SCRN'	System	05 Oct 2020 21:35:57

US3252624

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:24

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered (b) (6) 1987'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Oct 2020 21:22:50

US3252624

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:24

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered '33'	(b) (4), (b) (6)	05 Oct 2020 21:36:14

**US3252624**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:14:24**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered 'YEARS'	System	05 Oct 2020 21:36:14



**US3252624**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:14:24**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered '33'	System	05 Oct 2020 21:36:26

US3252624

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:24

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Female (F)'	(b) (4), (b) (6)	05 Oct 2020 21:36:14

US3252624

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:24

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	05 Oct 2020 21:36:14

**US3252624**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:14:24**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'I'	(b) (4), (b) (6)	05 Oct 2020 21:36:14

US3252624

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:24

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 21:36:14

**US3252624**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:14:24**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 21:36:14

US3252624

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:24

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 21:36:14

**US3252624**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:14:24**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 21:36:14



**US3252624**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:14:24**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 21:36:14

US3252624

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:14:24

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 21:36:14

**US3252624**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:14:24**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 21:36:14

**US3252624**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:14:24**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered '0'	(b) (4), (b) (6)	05 Oct 2020 21:36:14

US3252624

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:24

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 21:36:26

**US3252624**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered 'Oct 2020'	System	05 Oct 2020 21:36:26

**US3252624**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered '2020'	System	05 Oct 2020 21:36:26

**US3252624**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:14:24**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	05 Oct 2020 21:36:26



US3252624

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 21:36:26

US3252624

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:24

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 21:36:26

US3252624

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:24

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 21:36:26

**US3252624**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:14:24**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	(b) (4), (b) (6)	05 Oct 2020 21:36:26

US3252624

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:24

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	RWS_ENDPOINT	05 Oct 2020 21:22:49
	ENDPOINT (b) (4)	

US3252624

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:14:24

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered 'I'	System	05 Oct 2020 21:36:30

US3252624

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 21:36:30

US3252624

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:14:24

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:31:57



US3252624

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:34:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:34:16
Data point term sent to Coder	System	06 Oct 2020 16:33:14
User entered 'Hypertension'	(b) (4), (b) (6)	06 Oct 2020 16:32:20

US3252624

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'UN UNK 2016'	(b) (4), (b) (6)	06 Oct 2020 16:32:20

US3252624

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:32:20

US3252624

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:32:20

**US3252624**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:32:20

**US3252624**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:32:20

**US3252624**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered 'Jan 2016'	System	06 Oct 2020 16:32:20

US3252624

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered '2016'	System	06 Oct 2020 16:32:20



US3252624

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered empty.	System	06 Oct 2020 16:32:20

**US3252624**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered empty.	System	06 Oct 2020 16:32:20

US3252624

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	25 Mar 2021 19:38:40
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 02:26:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	10 Mar 2021 02:26:11
User entered 'diabetes type 2'	(b) (4), (b) (6)	10 Mar 2021 02:25:49

**US3252624**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	25 Mar 2021 19:38:40
User entered 'un Mar 2016'	(b) (4), (b) (6)	10 Mar 2021 02:25:49

**US3252624**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	25 Mar 2021 19:38:40
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 02:25:49

**US3252624**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	25 Mar 2021 19:38:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 02:25:49

**US3252624**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	25 Mar 2021 19:38:40
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 02:25:49

**US3252624**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	25 Mar 2021 19:38:40
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 02:25:49



US3252624

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered 'Mar 2016'	System	10 Mar 2021 02:25:49

**US3252624**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered '2016'	System	10 Mar 2021 02:25:49

**US3252624**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered empty.	System	10 Mar 2021 02:25:49

**US3252624**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered empty.	System	10 Mar 2021 02:25:49

**US3252624**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:14:24**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:33:16

US3252624

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '05 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 16:33:16

US3252624

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '16:09'	(b) (4), (b) (6)	06 Oct 2020 16:33:16

**US3252624**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered '05 Oct 2020 16:09'	System	06 Oct 2020 16:33:16



US3252624

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '66' in	(b) (4), (b) (6)	06 Oct 2020 16:33:16
DataPoint set to visible.	System	05 Oct 2020 21:36:30

US3252624

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '328' lb	(b) (4), (b) (6)	06 Oct 2020 16:33:16
DataPoint set to visible.	System	05 Oct 2020 21:36:30

US3252624

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered '53.05128'	System	06 Oct 2020 16:33:16
DataPoint set to visible.	System	05 Oct 2020 21:36:30

**US3252624**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:14:24**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered 'kg/m2'	System	06 Oct 2020 16:33:16
DataPoint set to visible.	System	05 Oct 2020 21:36:30

US3252624

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Oct 2020 16:33:16

US3252624

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:33:16

US3252624

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:33:16

US3252624

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Oct 2020 16:33:16



**US3252624**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:14:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered 'bpm'	System	06 Oct 2020 16:33:16

US3252624

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Oct 2020 16:33:16

US3252624

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered 'breaths/min'	System	06 Oct 2020 16:33:16

US3252624

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Oct 2020 16:33:16

**US3252624**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:14:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered 'mmHg'	System	06 Oct 2020 16:33:16

US3252624

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Oct 2020 16:33:16

US3252624

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered 'mmHg'	System	06 Oct 2020 16:33:16

US3252624

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34



US3252624

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34

US3252624

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:34:10

US3252624

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:24

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '05 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 16:34:10

US3252624

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:14:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered '05 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 16:34:25

US3252624

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:14:24

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:34:25

US3252624

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:14:24

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:34:25

US3252624

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:14:24

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:34:25

US3252624

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:14:24

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:34:25



US3252624

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:14:24

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:34:25

US3252624

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:34:25

US3252624

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:14:24

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:34:25

US3252624

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:14:24

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Nancy Torrence (b) (4)	06 Oct 2020 18:07:32
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:34:32

US3252624

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:14:24

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '5 Oct 2020' reason for change: Data Entry Error	Nancy Torrence (b) (4)	06 Oct 2020 18:07:32
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:34:32

**US3252624**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 16:14:24**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Urine (URINE)' reason for change:	Nancy Torrence (b) (4)	06 Oct 2020 18:07:32
Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:34:32

US3252624

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:14:24

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	Nancy Torrence (b) (4)	06 Oct 2020 18:07:32
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 16:34:32

US3252624

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:14:24

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)' reason for change: Data Entry Error	Nancy Torrence (b) (4)	06 Oct 2020 18:07:32
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:34:32



**US3252624**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 16:14:24**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:34:32

**US3252624**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 16:14:24**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:34:32

**US3252624**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered empty.	System	06 Oct 2020 16:34:32

US3252624

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:35:04

US3252624

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:35:04

US3252624

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:35:04

US3252624

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:35:04

US3252624

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:35:04



US3252624

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)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:35:04

US3252624

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:35:04

US3252624

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:35:04

US3252624

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:35:04

US3252624

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:35:04

US3252624

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:35:04

US3252624

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:35:04

US3252624

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Pet Groomer'	(b) (4), (b) (6)	06 Oct 2020 16:35:04



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:35:04

US3252624

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:35:04

US3252624

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:35:04

US3252624

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:35:04

US3252624

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:35:04

US3252624

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'I'	(b) (4), (b) (6)	06 Oct 2020 16:35:04

US3252624

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:35:04

US3252624

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:14:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:35:04



US3252624

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:14:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:35:19

**US3252624**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '05 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 16:35:19

US3252624

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Oct 2020 16:35:19

US3252624

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:14:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'VISIT1'	System	06 Oct 2020 16:35:19

US3252624

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '05 OCT 2020'	RWS_ENDPOINT	05 Oct 2020 21:42:44
	ENDPOINT (b) (4)	

US3252624

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '146942'	RWS_ENDPOINT	05 Oct 2020 21:42:44
	ENDPOINT (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Oct 2020 21:42:44

US3252624

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:24

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:35:45



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:24

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:35:45

US3252624

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:35:45

**US3252624**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:14:24**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:35:45

US3252624

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:14:24

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:35:45

**US3252624**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:35:45
DataPoint set to visible.	System	05 Oct 2020 21:36:26

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Oct 2020 16:37:11



US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Oct 2020 16:37:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:37:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '05 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '16:09'	(b) (4), (b) (6)	06 Oct 2020 16:37:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered '05 Oct 2020 16:09'	System	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '97.7' F	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Oct 2020 16:37:11



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '64'	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'bpm'	System	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '17'	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'breaths/min'	System	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '116'	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'mmHg'	System	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '80'	(b) (4), (b) (6)	06 Oct 2020 16:37:11



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'mmHg'	System	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:14:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Oct 2020 16:37:11

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '05 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '17:27'	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered '05 Oct 2020 17:27'	System	06 Oct 2020 16:37:11



US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '98.0' F	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '59'	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'bpm'	System	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '18'	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'breaths/min'	System	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '134'	(b) (4), (b) (6)	06 Oct 2020 16:37:11



US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'mmHg'	System	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '90'	(b) (4), (b) (6)	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'mmHg'	System	06 Oct 2020 16:37:11

US3252624

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:37:20

US3252624

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:24

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:37:20

US3252624

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:14:24

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)' reason for change: Data Entry	Nancy Torrence (b) (4)	06 Oct 2020 18:12:06
Error	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:37:46

US3252624

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:14:24

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty; reason for change Data Entry Error	Nancy Torrence (b) (4)	06 Oct 2020 18:12:06
User entered '05 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 16:37:46

US3252624

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:14:24

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty; reason for change Data Entry	Nancy Torrence (b) (4)	06 Oct 2020 18:12:06
Error	(b) (4)	
User entered 'Urine (URINE)'	(b) (4), (b) (6)	06 Oct 2020 16:37:46



US3252624

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:14:24

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty; reason for change Data Entry Error	Nancy Torrence (b) (4)	06 Oct 2020 18:12:06
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	06 Oct 2020 16:37:46

US3252624

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:14:24

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User closed query 'Per CDM: As per CCG, if Screening and dosing (VID1) are done on the same day "No" should be updated to avoid duplication. Please update the field. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:30:34
Query 'Per CDM: As per CCG, if Screening and dosing (VID1) are done on the same day "No" should be updated to avoid duplication. Please update the field. ' answered with 'updated' (Site from DM).	Nancy Torrence (b) (4)	16 Oct 2020 06:08:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	16 Oct 2020 06:08:16
User opened query 'Per CDM: As per CCG, if Screening and dosing (VID1) are done on the same day "No" should be updated to avoid duplication. Please update the field. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 23:41:23
User entered empty; reason for change Data Entry Error	Nancy Torrence (b) (4)	06 Oct 2020 18:12:06
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:37:46

**US3252624**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 16:14:24**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:37:46

US3252624

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:14:24

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:37:46

**US3252624**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered empty.	System	06 Oct 2020 16:37:46

US3252624

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	05 Oct 2020 22:00:45

US3252624

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Oct 2020 22:00:45

US3252624

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	Joanna Gurrola Mahoney (b) (4)	05 Oct 2020 22:00:45



US3252624

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'MRNA-1273 OR PLACEBO'	System	05 Oct 2020 22:00:45

US3252624

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '5 Oct 2020'	Joanna Gurrola Mahoney (b) (4)	05 Oct 2020 22:00:45

US3252624

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '16:57'	Joanna Gurrola Mahoney (b) (4)	05 Oct 2020 22:00:45

US3252624

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered '5 Oct 2020 16:57'	System	05 Oct 2020 22:00:45

US3252624

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola Mahoney	05 Oct 2020 22:00:45
	(b) (4)	

US3252624

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'ONCE'	System	05 Oct 2020 22:00:45

US3252624

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'INTRAMUSCULAR'	System	05 Oct 2020 22:00:45

US3252624

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:38:18



US3252624

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '05 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 16:38:18

**US3252624**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:14:24**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '16:50'	(b) (4), (b) (6)	06 Oct 2020 16:38:18

**US3252624**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered '05 Oct 2020 16:50'	System	06 Oct 2020 16:38:18

US3252624

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:14:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '05 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 16:38:39

US3252624

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	06 Oct 2020 16:38:39

US3252624

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:38:39

US3252624

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '16:43'	(b) (4), (b) (6)	06 Oct 2020 16:38:39

**US3252624**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered '05 Oct 2020 16:43'	System	06 Oct 2020 16:38:39



**US3252624**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	06 Oct 2020 16:38:39

US3252624

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:38:39

US3252624

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:38:39

**US3252624**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered empty.	System	06 Oct 2020 16:38:39

US3252624

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:38:52

US3252624

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:14:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'I'	System	06 Oct 2020 16:38:52

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T17:26:54', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '12b46bb4-ff1b-4be2-8430-f8a812e5f560'	System	05 Oct 2020 22:27:12
User entered 'Yes (Y)'	System	05 Oct 2020 22:27:12



US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T17:26:58', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '12b46bb4-ff1b-4be2-8430-f8a812e5f560' User entered '98.0'	System	05 Oct 2020 22:27:12
	System	05 Oct 2020 22:27:12

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T17:27:02', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '12b46bb4-ff1b-4be2-8430-f8a812e5f560'	System	05 Oct 2020 22:27:12
User entered 'No (N)'	System	05 Oct 2020 22:27:12

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T17:27:09', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '12b46bb4-ff1b-4be2-8430-f8a812e5f560' User entered '05 Oct 2020 17:27'	System	05 Oct 2020 22:27:12
	System	05 Oct 2020 22:27:12

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '05 Oct 2020 17:17'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '05 Oct 2020 19:47'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T23:39:36', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'd50299fa-b897-457c-a27b-1a13411bdfb7'	System	06 Oct 2020 04:40:12
User entered 'Yes (Y)'	System	06 Oct 2020 04:40:12

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T23:39:49', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'd50299fa-b897-457c-a27b-1a13411bdfb7' User entered '97.3'	System	06 Oct 2020 04:40:12
	System	06 Oct 2020 04:40:12



US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T23:39:57', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'd50299fa-b897-457c-a27b-1a13411bdfb7'	System	06 Oct 2020 04:40:12
User entered 'No (N)'	System	06 Oct 2020 04:40:12

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T23:40:10', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'd50299fa-b897-457c-a27b-1a13411bdfb7' User entered '05 Oct 2020 23:40'	System	06 Oct 2020 04:40:12
	System	06 Oct 2020 04:40:12

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '05 Oct 2020 20:42'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 2'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:14:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:26:34', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '212c01b7-aa72-4acb-8ac0-0b7da7245d51' User entered 'Yes (Y)'	System	07 Oct 2020 01:26:58
	System	07 Oct 2020 01:26:58

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:14:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:26:39', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '212c01b7-aa72-4acb-8ac0-0b7da7245d51' User entered '98.0'	System	07 Oct 2020 01:26:58
	System	07 Oct 2020 01:26:58

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:26:45', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '212c01b7-aa72-4acb-8ac0-0b7da7245d51'	System	07 Oct 2020 01:26:58
User entered 'Yes (Y)'	System	07 Oct 2020 01:26:58



US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant was contacted and reported medication details.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 16:37:09
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Joanna Gurrola Mahoney	12 Oct 2020 15:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:26:52', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '212c01b7-aa72-4acb-8ac0-0b7da7245d51'	(b) (4)	
User entered '1'	System	07 Oct 2020 01:26:58

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:14:24

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:26:52', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '212c01b7-aa72-4acb-8ac0-0b7da7245d51'	System	07 Oct 2020 01:26:58
User entered '0'	System	07 Oct 2020 01:26:58

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:26:55', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '212c01b7-aa72-4acb-8ac0-0b7da7245d51' User entered '06 Oct 2020 20:26'	System	07 Oct 2020 01:26:58
	System	07 Oct 2020 01:26:58

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 3'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:14:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-07T19:28:09', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'af0db1b9-fafc-47ed-99f0-a7bfa630366c' User entered 'Yes (Y)'	System	08 Oct 2020 00:28:23
	System	08 Oct 2020 00:28:23

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:14:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-07T19:28:13', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'af0db1b9-fafc-47ed-99f0-a7bfa630366c' User entered '98.7'	System	08 Oct 2020 00:28:23
	System	08 Oct 2020 00:28:23



US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-07T19:28:16', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'af0db1b9-fafc-47ed-99f0-a7bfa630366c' User entered 'No (N)'	System	08 Oct 2020 00:28:23
	System	08 Oct 2020 00:28:23

**US3252624**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:14:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-07T19:28:19', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'af0db1b9-fafc-47ed-99f0-a7bfa630366c' User entered '07 Oct 2020 19:28'	System	08 Oct 2020 00:28:23
	System	08 Oct 2020 00:28:23

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 4'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:14:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-08T23:11:18', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8a5b26d2-3223-4ac6-a1ec-165c3f20178a' User entered 'Yes (Y)'	System	09 Oct 2020 04:11:36
	System	09 Oct 2020 04:11:36

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:14:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-08T23:11:26', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8a5b26d2-3223-4ac6-a1ec-165c3f20178a' User entered '97.5'	System	09 Oct 2020 04:11:36
	System	09 Oct 2020 04:11:36

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-08T23:11:29', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8a5b26d2-3223-4ac6-a1ec-165c3f20178a' User entered 'No (N)'	System	09 Oct 2020 04:11:36
	System	09 Oct 2020 04:11:36



US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-08T23:11:33', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8a5b26d2-3223-4ac6-a1ec-165c3f20178a' User entered '08 Oct 2020 23:11'	System	09 Oct 2020 04:11:36
	System	09 Oct 2020 04:11:36

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 5'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:14:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:14:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37



US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:14:24

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 6'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:14:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-10T22:12:34', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9739990c-c0dd-4252-a4a8-9f1b0f77fee3' User entered 'Yes (Y)'	System	11 Oct 2020 03:12:52
	System	11 Oct 2020 03:12:52

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:14:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-10T22:12:39', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9739990c-c0dd-4252-a4a8-9f1b0f77fee3' User entered '97.5'	System	11 Oct 2020 03:12:52
	System	11 Oct 2020 03:12:52

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-10T22:12:45', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9739990c-c0dd-4252-a4a8-9f1b0f77fee3' User entered 'No (N)'	System	11 Oct 2020 03:12:52
	System	11 Oct 2020 03:12:52



US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-10T22:12:50', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9739990c-c0dd-4252-a4a8-9f1b0f77fee3' User entered '10 Oct 2020 22:12'	System	11 Oct 2020 03:12:52
	System	11 Oct 2020 03:12:52

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 7'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:14:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-11T23:45:05', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'eda20f25-d8ff-4008-a268-a19544981b01' User entered 'Yes (Y)'	System	12 Oct 2020 04:45:18
	System	12 Oct 2020 04:45:18

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:14:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-11T23:45:09', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'eda20f25-d8ff-4008-a268-a19544981b01' User entered '96.9'	System	12 Oct 2020 04:45:18
	System	12 Oct 2020 04:45:18

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-11T23:45:12', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'eda20f25-d8ff-4008-a268-a19544981b01'	System	12 Oct 2020 04:45:18
User entered 'No (N)'	System	12 Oct 2020 04:45:18

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-11T23:45:14', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'eda20f25-d8ff-4008-a268-a19544981b01'	System	12 Oct 2020 04:45:18
User entered '11 Oct 2020 23:45'	System	12 Oct 2020 04:45:18



US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T17:27:22', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '6f073f9f-1fa6-4770-a242-772479d5a1e8'	System	05 Oct 2020 22:27:43
User entered 'None (1)'	System	05 Oct 2020 22:27:43

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T17:27:26', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '6f073f9f-1fa6-4770-a242-772479d5a1e8'	System	05 Oct 2020 22:27:43
User entered 'No (N)'	System	05 Oct 2020 22:27:43

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T17:27:30', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '6f073f9f-1fa6-4770-a242-772479d5a1e8'	System	05 Oct 2020 22:27:43
User entered 'No (N)'	System	05 Oct 2020 22:27:43

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T17:27:39', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '6f073f9f-1fa6-4770-a242-772479d5a1e8' User entered 'None (1)'	System	05 Oct 2020 22:27:43
	System	05 Oct 2020 22:27:43

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T17:27:41', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '6f073f9f-1fa6-4770-a242-772479d5a1e8' User entered '05 Oct 2020 17:27'	System	05 Oct 2020 22:27:43
	System	05 Oct 2020 22:27:43



US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '05 Oct 2020 17:17'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '05 Oct 2020 19:47'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T23:40:49', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '4d5e73de-0e2a-4d6c-9ac4-a4aa7c1135eb' User entered 'Does not interfere with activity (2)'	System	06 Oct 2020 04:42:40
	System	06 Oct 2020 04:42:40

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T23:40:59', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '4d5e73de-0e2a-4d6c-9ac4-a4aa7c1135eb' User entered 'Yes (Y)'	System	06 Oct 2020 04:42:40
	System	06 Oct 2020 04:42:40

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T23:42:08', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '4d5e73de-0e2a-4d6c-9ac4-a4aa7c1135eb' User entered '1'	System	06 Oct 2020 04:42:40
	System	06 Oct 2020 04:42:40

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T23:42:14', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '4d5e73de-0e2a-4d6c-9ac4-a4aa7c1135eb' User entered 'Yes (Y)'	System	06 Oct 2020 04:42:40
	System	06 Oct 2020 04:42:40

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T23:42:20', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '4d5e73de-0e2a-4d6c-9ac4-a4aa7c1135eb' User entered '1'	System	06 Oct 2020 04:42:40
	System	06 Oct 2020 04:42:40



US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T23:42:28', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '4d5e73de-0e2a-4d6c-9ac4-a4aa7c1135eb' User entered 'None (1)'	System	06 Oct 2020 04:42:40
	System	06 Oct 2020 04:42:40

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T23:42:36', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '4d5e73de-0e2a-4d6c-9ac4-a4aa7c1135eb' User entered '05 Oct 2020 23:42'	System	06 Oct 2020 04:42:40
	System	06 Oct 2020 04:42:40

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '05 Oct 2020 20:42'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 2'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:19:36', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '63645af9-6678-441f-a3fe-513c8d06dd0a'	System	07 Oct 2020 01:26:30
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	07 Oct 2020 01:26:30

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:23:02', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '63645af9-6678-441f-a3fe-513c8d06dd0a' User entered 'Yes (Y)'	System	07 Oct 2020 01:26:30
	System	07 Oct 2020 01:26:30

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:25:37', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '63645af9-6678-441f-a3fe-513c8d06dd0a' User entered '40'	System	07 Oct 2020 01:26:30
	System	07 Oct 2020 01:26:30



US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:25:40', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '63645af9-6678-441f-a3fe-513c8d06dd0a' User entered 'Yes (Y)'	System	07 Oct 2020 01:26:30
	System	07 Oct 2020 01:26:30

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:25:55', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '63645af9-6678-441f-a3fe-513c8d06dd0a' User entered '20'	System	07 Oct 2020 01:26:30
	System	07 Oct 2020 01:26:30

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:26:19', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '63645af9-6678-441f-a3fe-513c8d06dd0a' User entered 'None (1)'	System	07 Oct 2020 01:26:30
	System	07 Oct 2020 01:26:30

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:26:27', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '63645af9-6678-441f-a3fe-513c8d06dd0a' User entered '06 Oct 2020 20:26'	System	07 Oct 2020 01:26:30
	System	07 Oct 2020 01:26:30

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 3'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-07T19:28:24', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '96fb887e-23f9-47e7-9c9d-68733ab88dbc'	System	08 Oct 2020 00:28:52
User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 00:28:52



US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-07T19:28:26', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '96fb887e-23f9-47e7-9c9d-68733ab88dbc' User entered 'Yes (Y)'	System	08 Oct 2020 00:28:52
	System	08 Oct 2020 00:28:52

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-07T19:28:29', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '96fb887e-23f9-47e7-9c9d-68733ab88dbc' User entered '46'	System	08 Oct 2020 00:28:52
	System	08 Oct 2020 00:28:52

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-07T19:28:33', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '96fb887e-23f9-47e7-9c9d-68733ab88dbc' User entered 'Yes (Y)'	System	08 Oct 2020 00:28:52
	System	08 Oct 2020 00:28:52

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-07T19:28:41', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '96fb887e-23f9-47e7-9c9d-68733ab88dbc' User entered '30'	System	08 Oct 2020 00:28:52
	System	08 Oct 2020 00:28:52

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-07T19:28:46', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '96fb887e-23f9-47e7-9c9d-68733ab88dbc' User entered 'None (1)'	System	08 Oct 2020 00:28:52
	System	08 Oct 2020 00:28:52

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-07T19:28:49', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '96fb887e-23f9-47e7-9c9d-68733ab88dbc' User entered '07 Oct 2020 19:28'	System	08 Oct 2020 00:28:52
	System	08 Oct 2020 00:28:52

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 22:00:45



US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 4'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-08T23:11:39', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '4018bf14-db45-41fd-84f8-3a5899525e88'	System	09 Oct 2020 04:12:04
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 04:12:04

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-08T23:11:42', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '4018bf14-db45-41fd-84f8-3a5899525e88'	System	09 Oct 2020 04:12:04
User entered 'Yes (Y)'	System	09 Oct 2020 04:12:04

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-08T23:11:47', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '4018bf14-db45-41fd-84f8-3a5899525e88' User entered '43'	System	09 Oct 2020 04:12:04
	System	09 Oct 2020 04:12:04

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-08T23:11:50', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '4018bf14-db45-41fd-84f8-3a5899525e88'	System	09 Oct 2020 04:12:04
User entered 'Yes (Y)'	System	09 Oct 2020 04:12:04

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-08T23:11:54', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '4018bf14-db45-41fd-84f8-3a5899525e88'	System	09 Oct 2020 04:12:04
User entered '30'	System	09 Oct 2020 04:12:04

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-08T23:11:58', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '4018bf14-db45-41fd-84f8-3a5899525e88'	System	09 Oct 2020 04:12:04
User entered 'None (1)'	System	09 Oct 2020 04:12:04

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-08T23:12:01', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '4018bf14-db45-41fd-84f8-3a5899525e88' User entered '08 Oct 2020 23:12'	System	09 Oct 2020 04:12:04
	System	09 Oct 2020 04:12:04



US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 5'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37



US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 6'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-10T22:12:55', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9ddf25bc-d6cc-4507-852c-e78921f45e41' User entered 'None (1)'	System	11 Oct 2020 03:13:08
	System	11 Oct 2020 03:13:08

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:14:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-10T22:12:57', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9ddf25bc-d6cc-4507-852c-e78921f45e41' User entered 'No (N)'	System	11 Oct 2020 03:13:08
	System	11 Oct 2020 03:13:08

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-10T22:12:59', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9ddf25bc-d6cc-4507-852c-e78921f45e41' User entered 'No (N)'	System	11 Oct 2020 03:13:08
	System	11 Oct 2020 03:13:08



US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-10T22:13:01', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9ddf25bc-d6cc-4507-852c-e78921f45e41' User entered 'None (1)'	System	11 Oct 2020 03:13:08
	System	11 Oct 2020 03:13:08

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-10T22:13:06', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9ddf25bc-d6cc-4507-852c-e78921f45e41' User entered '10 Oct 2020 22:13'	System	11 Oct 2020 03:13:08
	System	11 Oct 2020 03:13:08

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 7'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-11T23:45:19', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e9503d4a-f6b0-45db-8e74-aa1f99065952'	System	12 Oct 2020 04:45:40
User entered 'None (1)'	System	12 Oct 2020 04:45:40

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:14:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-11T23:45:31', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e9503d4a-f6b0-45db-8e74-aa1f99065952' User entered 'No (N)'	System	12 Oct 2020 04:45:40
	System	12 Oct 2020 04:45:40

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-11T23:45:33', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e9503d4a-f6b0-45db-8e74-aa1f99065952' User entered 'No (N)'	System	12 Oct 2020 04:45:40
	System	12 Oct 2020 04:45:40



US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-11T23:45:35', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e9503d4a-f6b0-45db-8e74-aa1f99065952' User entered 'None (1)'	System	12 Oct 2020 04:45:40
	System	12 Oct 2020 04:45:40

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-11T23:45:37', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e9503d4a-f6b0-45db-8e74-aa1f99065952' User entered '11 Oct 2020 23:45'	System	12 Oct 2020 04:45:40
	System	12 Oct 2020 04:45:40

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T17:27:51', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'fd695f04-9753-4517-b3bc-4348ed1a5d83'	System	05 Oct 2020 22:28:21
User entered 'None (0)'	System	05 Oct 2020 22:28:21

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T17:27:54', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'fd695f04-9753-4517-b3bc-4348ed1a5d83' User entered 'None (0)'	System	05 Oct 2020 22:28:21
	System	05 Oct 2020 22:28:21

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T17:27:56', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'fd695f04-9753-4517-b3bc-4348ed1a5d83' User entered 'None (0)'	System	05 Oct 2020 22:28:21
	System	05 Oct 2020 22:28:21



US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T17:28:03', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'fd695f04-9753-4517-b3bc-4348ed1a5d83' User entered 'None (0)'	System	05 Oct 2020 22:28:21
	System	05 Oct 2020 22:28:21

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T17:28:05', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'fd695f04-9753-4517-b3bc-4348ed1a5d83'	System	05 Oct 2020 22:28:21
User entered 'None (0)'	System	05 Oct 2020 22:28:21

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T17:28:07', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'fd695f04-9753-4517-b3bc-4348ed1a5d83'	System	05 Oct 2020 22:28:21
User entered 'None (0)'	System	05 Oct 2020 22:28:21

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

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)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T17:28:13', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'fd695f04-9753-4517-b3bc-4348ed1a5d83'	System	05 Oct 2020 22:28:21
User entered 'No (N)'	System	05 Oct 2020 22:28:21

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T17:28:15', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'fd695f04-9753-4517-b3bc-4348ed1a5d83'	System	05 Oct 2020 22:28:21
User entered '05 Oct 2020 17:28'	System	05 Oct 2020 22:28:21

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '05 Oct 2020 17:17'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '05 Oct 2020 19:47'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 22:00:45



US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T23:42:52', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e230ab33-e853-41a2-8462-57f246496a49' User entered 'None (0)'	System	06 Oct 2020 04:43:22
	System	06 Oct 2020 04:43:22

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T23:42:57', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e230ab33-e853-41a2-8462-57f246496a49' User entered 'None (0)'	System	06 Oct 2020 04:43:22
	System	06 Oct 2020 04:43:22

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T23:43:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e230ab33-e853-41a2-8462-57f246496a49' User entered 'None (0)'	System	06 Oct 2020 04:43:22
	System	06 Oct 2020 04:43:22

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T23:43:03', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e230ab33-e853-41a2-8462-57f246496a49' User entered 'None (0)'	System	06 Oct 2020 04:43:22
	System	06 Oct 2020 04:43:22

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T23:43:06', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e230ab33-e853-41a2-8462-57f246496a49' User entered 'None (0)'	System	06 Oct 2020 04:43:22
	System	06 Oct 2020 04:43:22

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T23:43:07', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e230ab33-e853-41a2-8462-57f246496a49' User entered 'None (0)'	System	06 Oct 2020 04:43:22
	System	06 Oct 2020 04:43:22

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

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)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T23:43:17', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e230ab33-e853-41a2-8462-57f246496a49' User entered 'No (N)'	System	06 Oct 2020 04:43:22
	System	06 Oct 2020 04:43:22

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-05T23:43:19', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e230ab33-e853-41a2-8462-57f246496a49' User entered '05 Oct 2020 23:43'	System	06 Oct 2020 04:43:22
	System	06 Oct 2020 04:43:22



US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '05 Oct 2020 20:42'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 2'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:18:44', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '10e7000f-5059-4b87-885b-f01c368f7024' User entered 'None (0)'	System	07 Oct 2020 01:19:24
	System	07 Oct 2020 01:19:24

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:18:48', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '10e7000f-5059-4b87-885b-f01c368f7024'	System	07 Oct 2020 01:19:24
User entered 'No interference with activity (1)'	System	07 Oct 2020 01:19:24

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:18:54', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '10e7000f-5059-4b87-885b-f01c368f7024' User entered 'None (0)'	System	07 Oct 2020 01:19:24
	System	07 Oct 2020 01:19:24

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:19:06', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '10e7000f-5059-4b87-885b-f01c368f7024' User entered 'None (0)'	System	07 Oct 2020 01:19:24
	System	07 Oct 2020 01:19:24

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:19:09', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '10e7000f-5059-4b87-885b-f01c368f7024' User entered 'None (0)'	System	07 Oct 2020 01:19:24
	System	07 Oct 2020 01:19:24



US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:19:11', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '10e7000f-5059-4b87-885b-f01c368f7024' User entered 'None (0)'	System	07 Oct 2020 01:19:24
	System	07 Oct 2020 01:19:24

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

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)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:19:14', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '10e7000f-5059-4b87-885b-f01c368f7024' User entered 'No (N)'	System	07 Oct 2020 01:19:24
	System	07 Oct 2020 01:19:24

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-06T20:19:20', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '10e7000f-5059-4b87-885b-f01c368f7024' User entered '06 Oct 2020 20:19'	System	07 Oct 2020 01:19:24
	System	07 Oct 2020 01:19:24

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 3'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-07T19:28:53', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9fb61bd6-54e1-4c9d-ab26-d6ed23e41c5c' User entered 'None (0)'	System	08 Oct 2020 00:29:17
	System	08 Oct 2020 00:29:17

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-07T19:28:57', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9fb61bd6-54e1-4c9d-ab26-d6ed23e41c5c'	System	08 Oct 2020 00:29:17
User entered 'No interference with activity (1)'	System	08 Oct 2020 00:29:17



US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-07T19:29:01', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9fb61bd6-54e1-4c9d-ab26-d6ed23e41c5c' User entered 'None (0)'	System	08 Oct 2020 00:29:17
	System	08 Oct 2020 00:29:17

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-07T19:29:03', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9fb61bd6-54e1-4c9d-ab26-d6ed23e41c5c' User entered 'None (0)'	System	08 Oct 2020 00:29:17
	System	08 Oct 2020 00:29:17

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-07T19:29:05', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9fb61bd6-54e1-4c9d-ab26-d6ed23e41c5c' User entered 'None (0)'	System	08 Oct 2020 00:29:17
	System	08 Oct 2020 00:29:17

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-07T19:29:06', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9fb61bd6-54e1-4c9d-ab26-d6ed23e41c5c' User entered 'None (0)'	System	08 Oct 2020 00:29:17
	System	08 Oct 2020 00:29:17

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

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)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-07T19:29:13', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9fb61bd6-54e1-4c9d-ab26-d6ed23e41c5c' User entered 'No (N)'	System	08 Oct 2020 00:29:17
	System	08 Oct 2020 00:29:17

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-07T19:29:15', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9fb61bd6-54e1-4c9d-ab26-d6ed23e41c5c' User entered '07 Oct 2020 19:29'	System	08 Oct 2020 00:29:17
	System	08 Oct 2020 00:29:17

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 22:00:45



US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 4'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-08T23:12:04', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'eaa69094-ec70-42bc-856a-f37710a117b9' User entered 'None (0)'	System	09 Oct 2020 04:12:29
	System	09 Oct 2020 04:12:29

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-08T23:12:13', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'eaa69094-ec70-42bc-856a-f37710a117b9'	System	09 Oct 2020 04:12:29
User entered 'No interference with activity (1)'	System	09 Oct 2020 04:12:29

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-08T23:12:16', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'eaa69094-ec70-42bc-856a-f37710a117b9' User entered 'None (0)'	System	09 Oct 2020 04:12:29
	System	09 Oct 2020 04:12:29

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-08T23:12:19', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'eaa69094-ec70-42bc-856a-f37710a117b9' User entered 'None (0)'	System	09 Oct 2020 04:12:29
	System	09 Oct 2020 04:12:29

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-08T23:12:20', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'eaa69094-ec70-42bc-856a-f37710a117b9' User entered 'None (0)'	System	09 Oct 2020 04:12:29
	System	09 Oct 2020 04:12:29

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-08T23:12:22', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'eaa69094-ec70-42bc-856a-f37710a117b9' User entered 'None (0)'	System	09 Oct 2020 04:12:29
	System	09 Oct 2020 04:12:29

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

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)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-08T23:12:25', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'eaa69094-ec70-42bc-856a-f37710a117b9' User entered 'No (N)'	System	09 Oct 2020 04:12:29
	System	09 Oct 2020 04:12:29



US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-08T23:12:28', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'eaa69094-ec70-42bc-856a-f37710a117b9' User entered '08 Oct 2020 23:12'	System	09 Oct 2020 04:12:29
	System	09 Oct 2020 04:12:29

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 5'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37



US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37

**US3252624**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:14:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

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)	26 Feb 2021 08:24:37

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 6'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-10T22:13:09', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '2df59321-92ee-4f5f-a45d-3369764f7cf1' User entered 'None (0)'	System	11 Oct 2020 03:13:35
	System	11 Oct 2020 03:13:35



US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-10T22:13:12', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '2df59321-92ee-4f5f-a45d-3369764f7cf1'	System	11 Oct 2020 03:13:35
User entered 'No interference with activity (1)'	System	11 Oct 2020 03:13:35

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-10T22:13:16', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '2df59321-92ee-4f5f-a45d-3369764f7cf1'	System	11 Oct 2020 03:13:35
User entered 'No interference with activity (1)'	System	11 Oct 2020 03:13:35

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-10T22:13:20', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '2df59321-92ee-4f5f-a45d-3369764f7cf1' User entered 'No interference with activity (1)'	System	11 Oct 2020 03:13:35
	System	11 Oct 2020 03:13:35

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-10T22:13:23', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '2df59321-92ee-4f5f-a45d-3369764f7cf1' User entered 'None (0)'	System	11 Oct 2020 03:13:35
	System	11 Oct 2020 03:13:35

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-10T22:13:25', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '2df59321-92ee-4f5f-a45d-3369764f7cf1' User entered 'None (0)'	System	11 Oct 2020 03:13:35
	System	11 Oct 2020 03:13:35

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

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)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-10T22:13:28', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '2df59321-92ee-4f5f-a45d-3369764f7cf1' User entered 'No (N)'	System	11 Oct 2020 03:13:35
	System	11 Oct 2020 03:13:35

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-10T22:13:32', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '2df59321-92ee-4f5f-a45d-3369764f7cf1' User entered '10 Oct 2020 22:13'	System	11 Oct 2020 03:13:35
	System	11 Oct 2020 03:13:35

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 22:00:45



US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	05 Oct 2020 22:00:45
User entered 'Day 7'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-11T23:44:25', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8094b4d8-101f-4e7a-9300-bb13a317e594' User entered 'None (0)'	System	12 Oct 2020 04:45:01
	System	12 Oct 2020 04:45:01

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-11T23:44:31', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8094b4d8-101f-4e7a-9300-bb13a317e594'	System	12 Oct 2020 04:45:01
User entered 'No interference with activity (1)'	System	12 Oct 2020 04:45:01

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-11T23:44:34', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8094b4d8-101f-4e7a-9300-bb13a317e594'	System	12 Oct 2020 04:45:01
User entered 'Some interference with activity (2)'	System	12 Oct 2020 04:45:01

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-11T23:44:43', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8094b4d8-101f-4e7a-9300-bb13a317e594'	System	12 Oct 2020 04:45:01
User entered 'No interference with activity (1)'	System	12 Oct 2020 04:45:01

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-11T23:44:46', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8094b4d8-101f-4e7a-9300-bb13a317e594' User entered 'None (0)'	System	12 Oct 2020 04:45:01
	System	12 Oct 2020 04:45:01

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-11T23:44:49', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8094b4d8-101f-4e7a-9300-bb13a317e594' User entered 'None (0)'	System	12 Oct 2020 04:45:01
	System	12 Oct 2020 04:45:01



US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

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)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-11T23:44:57', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8094b4d8-101f-4e7a-9300-bb13a317e594' User entered 'No (N)'	System	12 Oct 2020 04:45:01
	System	12 Oct 2020 04:45:01

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-11T23:44:59', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8094b4d8-101f-4e7a-9300-bb13a317e594' User entered '11 Oct 2020 23:44'	System	12 Oct 2020 04:45:01
	System	12 Oct 2020 04:45:01

US3252624

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 22:00:45

**US3252624**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:14:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 22:00:45

US3252624

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	11 Oct 2020 03:13:35
User entered 'Day 8'	System	11 Oct 2020 03:13:35

US3252624

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-12T23:59:16', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'b3e26fd2-8e07-4524-bf2f-9915fd9564e6'	System	13 Oct 2020 04:59:24
User entered 'No interference with activity (1)'	System	13 Oct 2020 04:59:24

US3252624

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-12T23:59:19', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'b3e26fd2-8e07-4524-bf2f-9915fd9564e6' User entered '12 Oct 2020 23:59'	System	13 Oct 2020 04:59:24
	System	13 Oct 2020 04:59:24

US3252624

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 03:13:35



**US3252624**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 16:14:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 03:13:35

US3252624

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	12 Oct 2020 04:45:01
User entered 'Day 9'	System	12 Oct 2020 04:45:01

US3252624

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-13T23:59:24', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '87ea0001-dc87-41c2-84a0-4ec11d5abfea' User entered 'None (0)'	System	14 Oct 2020 04:59:30
	System	14 Oct 2020 04:59:30

US3252624

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-13T23:59:27', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '87ea0001-dc87-41c2-84a0-4ec11d5abfea' User entered '13 Oct 2020 23:59'	System	14 Oct 2020 04:59:30
	System	14 Oct 2020 04:59:30

US3252624

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 04:45:01

US3252624

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 04:45:01

US3252624

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	11 Oct 2020 03:13:35
User entered 'Day 8'	System	11 Oct 2020 03:13:35

US3252624

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 16:14:24

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-12T23:59:25', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '3109e2c4-553d-4a90-845a-55b2f3163abf' User entered 'No interference with activity (1)'	System	13 Oct 2020 04:59:32
	System	13 Oct 2020 04:59:32



US3252624

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-12T23:59:28', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '3109e2c4-553d-4a90-845a-55b2f3163abf' User entered '12 Oct 2020 23:59'	System	13 Oct 2020 04:59:32
	System	13 Oct 2020 04:59:32

US3252624

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 03:13:35

US3252624

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 03:13:35

US3252624

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	12 Oct 2020 04:45:01
User entered 'Day 9'	System	12 Oct 2020 04:45:01

US3252624

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 16:14:24

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-13T23:59:30', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '4760d6c7-5b37-4c56-bb82-7c47aadd7d00' User entered 'None (0)'	System	14 Oct 2020 04:59:38
	System	14 Oct 2020 04:59:38

**US3252624**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 09 Jun 2021 16:14:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-13T23:59:32', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '4760d6c7-5b37-4c56-bb82-7c47aadd7d00' User entered '13 Oct 2020 23:59'	System	14 Oct 2020 04:59:38
	System	14 Oct 2020 04:59:38

US3252624

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 04:45:01

US3252624

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 04:45:01



US3252624

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	11 Oct 2020 03:13:35
User entered 'Day 8'	System	11 Oct 2020 03:13:35

US3252624

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-12T23:59:30', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'c81567a0-2d0f-44c6-bc26-a88fa5eb8048'	System	13 Oct 2020 04:59:37
User entered 'No interference with activity (1)'	System	13 Oct 2020 04:59:37

US3252624

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-12T23:59:32', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'c81567a0-2d0f-44c6-bc26-a88fa5eb8048' User entered '12 Oct 2020 23:59'	System	13 Oct 2020 04:59:37
	System	13 Oct 2020 04:59:37

**US3252624**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 09 Jun 2021 16:14:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 03:13:35

US3252624

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 03:13:35

US3252624

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	12 Oct 2020 04:45:01
User entered 'Day 9'	System	12 Oct 2020 04:45:01

US3252624

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-13T23:59:35', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e9e6e7c0-d4e0-4183-9ef5-e5f2f1d31500' User entered 'None (0)'	System	14 Oct 2020 04:59:41
	System	14 Oct 2020 04:59:41

US3252624

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-13T23:59:37', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e9e6e7c0-d4e0-4183-9ef5-e5f2f1d31500' User entered '13 Oct 2020 23:59'	System	14 Oct 2020 04:59:41
	System	14 Oct 2020 04:59:41



US3252624

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 04:45:01

**US3252624**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 09 Jun 2021 16:14:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 04:45:01

US3252624

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	11 Oct 2020 03:13:35
User entered 'Day 8'	System	11 Oct 2020 03:13:35

US3252624

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:14:24

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)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-12T23:59:35', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '5e257cd2-f45f-4b09-96ab-3c690c0ccb5e' User entered 'No (N)'	System	13 Oct 2020 04:59:43
	System	13 Oct 2020 04:59:43

US3252624

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-12T23:59:37', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '5e257cd2-f45f-4b09-96ab-3c690c0ccb5e' User entered '12 Oct 2020 23:59'	System	13 Oct 2020 04:59:43
	System	13 Oct 2020 04:59:43

US3252624

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '12 Oct 2020 12:00'	System	11 Oct 2020 03:13:35

US3252624

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '13 Oct 2020 11:59'	System	11 Oct 2020 03:13:35

US3252624

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	12 Oct 2020 04:45:01
User entered 'Day 9'	System	12 Oct 2020 04:45:01



US3252624

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:14:24

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)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-13T23:59:41', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e78d8972-0f9c-4ca4-9e05-bb88a9f6e05e' User entered 'No (N)'	System	14 Oct 2020 04:59:45
	System	14 Oct 2020 04:59:45

US3252624

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E68916F1-8C91-46F3-9540-2198073290EC)', Time: '2020-10-13T23:59:43', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e78d8972-0f9c-4ca4-9e05-bb88a9f6e05e' User entered '13 Oct 2020 23:59'	System	14 Oct 2020 04:59:45
	System	14 Oct 2020 04:59:45

US3252624

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 04:45:01

US3252624

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 04:45:01

US3252624

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	13 Oct 2020 02:39:24
	(b) (4)	

**US3252624**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered '12 Oct 2020'	Nancy Torrence (b) (4)	13 Oct 2020 02:39:24
	(b) (4)	

**US3252624**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	13 Oct 2020 02:39:24
	(b) (4)	

US3252624

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered empty.	Nancy Torrence (b) (4)	13 Oct 2020 02:39:24
	(b) (4)	



US3252624

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	13 Oct 2020 02:39:29
	(b) (4)	

US3252624

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'I'	System	13 Oct 2020 02:39:29

**US3252624**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	21 Oct 2020 08:34:53
	(b) (4)	

US3252624

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered '19 Oct 2020'	Nancy Torrence (b) (4)	21 Oct 2020 08:34:53
	(b) (4)	

**US3252624**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4)	21 Oct 2020 08:34:53
	(b) (4)	

US3252624

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered empty.	Nancy Torrence (b) (4)	21 Oct 2020 08:34:53
	(b) (4)	

US3252624

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	21 Oct 2020 08:34:58
	(b) (4)	

**US3252624**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:14:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'I'	System	21 Oct 2020 08:34:58



**US3252624**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 14:17:09

US3252624

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered '28 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 14:17:09

US3252624

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Oct 2020 14:17:09

US3252624

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 14:17:09

US3252624

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 14:17:15

US3252624

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'I'	System	29 Oct 2020 14:17:15

US3252624

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	05 Nov 2020 08:27:19
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '4 Nov 2020'	Nancy Torrence (b) (4)	05 Nov 2020 08:27:19
	(b) (4)	



US3252624

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Clinic (Clinic)'	Nancy Torrence (b) (4)	05 Nov 2020 08:27:19
	(b) (4)	

**US3252624**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:14:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'VISIT2'	System	05 Nov 2020 08:27:19

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User accepted default value 'Pre-Dose (PREDOSE)'	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '4 Nov 2020'	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '09:22'	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered '4 Nov 2020 09:22'	System	05 Nov 2020 08:29:50

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '97.7' F	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	



US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Oral (Oral)'	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '64'	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'bpm'	System	05 Nov 2020 08:29:50

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '15'	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'breaths/min'	System	05 Nov 2020 08:29:50

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '120'	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'mmHg'	System	05 Nov 2020 08:29:50



US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '81'	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:14:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'mmHg'	System	05 Nov 2020 08:29:50

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User accepted default value 'Post-Dose (POSTDOSE)'	Nancy Torrence (b) (4) (b) (4)	05 Nov 2020 08:29:50

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '4 Nov 2020'	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '10:53'	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered '4 Nov 2020 10:53'	System	05 Nov 2020 08:29:50

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '98.3' F	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Oral (Oral)'	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '65'	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'bpm'	System	05 Nov 2020 08:29:50

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '16'	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'breaths/min'	System	05 Nov 2020 08:29:50

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '129'	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'mmHg'	System	05 Nov 2020 08:29:50



US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '73'	Nancy Torrence (b) (4)	05 Nov 2020 08:29:50
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:14:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'mmHg'	System	05 Nov 2020 08:29:50

US3252624

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	Nancy Torrence (b) (4)	05 Nov 2020 08:30:02
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	Nancy Torrence (b) (4)	05 Nov 2020 08:30:02
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:14:24

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	05 Nov 2020 08:30:46
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:14:24

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '4 Nov 2020'	Nancy Torrence (b) (4)	05 Nov 2020 08:30:46
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:14:24

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Urine (URINE)'	Nancy Torrence (b) (4)	05 Nov 2020 08:30:46
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:14:24

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Negative (NEGATIVE)'	Nancy Torrence (b) (4)	05 Nov 2020 08:30:46
	(b) (4)	



US3252624

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:14:24

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	Nancy Torrence (b) (4)	05 Nov 2020 08:30:46
	(b) (4)	

**US3252624**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 16:14:24**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	Nancy Torrence (b) (4)	05 Nov 2020 08:30:46
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:14:24

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	Nancy Torrence (b) (4)	05 Nov 2020 08:30:46
	(b) (4)	

**US3252624**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered empty.	System	05 Nov 2020 08:30:46

US3252624

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	04 Nov 2020 16:25:05

US3252624

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	Joanna Gurrola Mahoney	04 Nov 2020 16:25:05
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	Joanna Gurrola Mahoney (b) (4)	04 Nov 2020 16:25:05

US3252624

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'MRNA-1273 OR PLACEBO'	System	04 Nov 2020 16:25:05



US3252624

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '4 Nov 2020'	Joanna Gurrola Mahoney (b) (4)	04 Nov 2020 16:25:05

US3252624

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '10:23'	Joanna Gurrola Mahoney (b) (4)	04 Nov 2020 16:25:05

US3252624

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered '4 Nov 2020 10:23'	System	04 Nov 2020 16:25:05

US3252624

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola Mahoney	04 Nov 2020 16:25:05
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'ONCE'	System	04 Nov 2020 16:25:05

US3252624

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:14:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'INTRAMUSCULAR'	System	04 Nov 2020 16:25:05

US3252624

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	05 Nov 2020 08:32:08
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '4 Nov 2020'	Nancy Torrence (b) (4)	05 Nov 2020 08:32:08
	(b) (4)	



**US3252624**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:14:24**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '10:12'	Nancy Torrence (b) (4)	05 Nov 2020 08:32:08
	(b) (4)	

**US3252624**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered '4 Nov 2020 10:12'	System	05 Nov 2020 08:32:08

US3252624

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:14:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '4 Nov 2020'	Nancy Torrence (b) (4)	05 Nov 2020 08:32:26
	(b) (4)	

**US3252624**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nancy Torrence (b) (4) (b) (4)	05 Nov 2020 08:32:26

US3252624

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	05 Nov 2020 08:32:26
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:14:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '10:04' reason for change: Data Entry	Nancy Torrence (b) (4)	05 Nov 2020 08:33:40
Error	(b) (4)	
User entered '10:12'	Nancy Torrence (b) (4)	05 Nov 2020 08:32:26
	(b) (4)	

**US3252624**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered '4 Nov 2020 10:04'	System	05 Nov 2020 08:33:40
User entered '4 Nov 2020 10:12'	System	05 Nov 2020 08:32:26

**US3252624**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nancy Torrence (b) (4) (b) (4)	05 Nov 2020 08:32:26



US3252624

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	Nancy Torrence (b) (4)	05 Nov 2020 08:32:26
	(b) (4)	

US3252624

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:14:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	Nancy Torrence (b) (4)	05 Nov 2020 08:32:26
	(b) (4)	

**US3252624**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered empty.	System	05 Nov 2020 08:32:26

US3252624

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	Nancy Torrence (b) (4)	05 Nov 2020 08:33:47
	(b) (4)	

**US3252624**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:14:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'I'	System	05 Nov 2020 08:33:47

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T10:54:12', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'f0853cc5-56e8-46c8-91d9-377f61f1314c' User entered 'Yes (Y)'	System	04 Nov 2020 16:54:48
	System	04 Nov 2020 16:54:48

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T10:54:17', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'f0853cc5-56e8-46c8-91d9-377f61f1314c' User entered '98.3'	System	04 Nov 2020 16:54:48
	System	04 Nov 2020 16:54:48



US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T10:54:37', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'f0853cc5-56e8-46c8-91d9-377f61f1314c' User entered 'Yes (Y)'	System	04 Nov 2020 16:54:48
	System	04 Nov 2020 16:54:48

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T10:54:40', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'f0853cc5-56e8-46c8-91d9-377f61f1314c' User entered '0'	System	04 Nov 2020 16:54:48
	System	04 Nov 2020 16:54:48

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient was contacted reports taking Ibuprofen' (Site from System).	(b) (4), (b) (6)	11 Feb 2021 09:43:14
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Uche Ehiemua (b) (4)	10 Feb 2021 14:51:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T10:54:40', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'f0853cc5-56e8-46c8-91d9-377f61f1314c'	System	04 Nov 2020 16:54:48
User entered '1'	System	04 Nov 2020 16:54:48

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T10:54:43', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'f0853cc5-56e8-46c8-91d9-377f61f1314c' User entered '04 Nov 2020 10:54'	System	04 Nov 2020 16:54:48
	System	04 Nov 2020 16:54:48

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '04 Nov 2020 10:43'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '04 Nov 2020 13:13'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 1, after vaccination (at home)'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:23:21', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '79264733-4795-43ae-9e31-c38ba14d9846' User entered 'Yes (Y)'	System	05 Nov 2020 04:23:42
	System	05 Nov 2020 04:23:42



US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:23:27', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '79264733-4795-43ae-9e31-c38ba14d9846' User entered '97.3'	System	05 Nov 2020 04:23:42
	System	05 Nov 2020 04:23:42

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:23:30', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '79264733-4795-43ae-9e31-c38ba14d9846'	System	05 Nov 2020 04:23:42
User entered 'Yes (Y)'	System	05 Nov 2020 04:23:42

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient was contacted reports taking Ibuprofen' (Site from System).	(b) (4), (b) (6)	11 Feb 2021 09:43:24
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Uche Ehiemua (b) (4)	10 Feb 2021 14:51:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:23:33', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '79264733-4795-43ae-9e31-c38ba14d9846'	System	05 Nov 2020 04:23:42
User entered '1'	System	05 Nov 2020 04:23:42

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:23:33', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '79264733-4795-43ae-9e31-c38ba14d9846' User entered '0'	System	05 Nov 2020 04:23:42
	System	05 Nov 2020 04:23:42

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:23:39', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '79264733-4795-43ae-9e31-c38ba14d9846' User entered '04 Nov 2020 22:23'	System	05 Nov 2020 04:23:42
	System	05 Nov 2020 04:23:42

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '04 Nov 2020 14:08'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '05 Nov 2020 11:59'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 2'	System	04 Nov 2020 16:25:05



US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:14:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-05T21:53:24', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'de8800a4-0af2-4956-8cd7-3dc01e92d833'	System	06 Nov 2020 03:53:58
User entered 'Yes (Y)'	System	06 Nov 2020 03:53:58

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:14:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-05T21:53:43', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'de8800a4-0af2-4956-8cd7-3dc01e92d833' User entered '98.8'	System	06 Nov 2020 03:53:58
	System	06 Nov 2020 03:53:58

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-05T21:53:50', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'de8800a4-0af2-4956-8cd7-3dc01e92d833'	System	06 Nov 2020 03:53:58
User entered 'No (N)'	System	06 Nov 2020 03:53:58

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-05T21:53:55', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'de8800a4-0af2-4956-8cd7-3dc01e92d833'	System	06 Nov 2020 03:53:58
User entered '05 Nov 2020 21:53'	System	06 Nov 2020 03:53:58

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '05 Nov 2020 12:00'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '06 Nov 2020 11:59'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 3'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:14:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-06T22:54:09', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '04b51497-9957-4e87-9158-cca7a344cd43'	System	07 Nov 2020 04:54:52
User entered 'Yes (Y)'	System	07 Nov 2020 04:54:52



US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:14:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-06T22:54:36', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '04b51497-9957-4e87-9158-cca7a344cd43' User entered '96.0'	System	07 Nov 2020 04:54:52
	System	07 Nov 2020 04:54:52

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-06T22:54:43', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '04b51497-9957-4e87-9158-cca7a344cd43'	System	07 Nov 2020 04:54:52
User entered 'No (N)'	System	07 Nov 2020 04:54:52

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-06T22:54:50', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '04b51497-9957-4e87-9158-cca7a344cd43' User entered '06 Nov 2020 22:54'	System	07 Nov 2020 04:54:52
	System	07 Nov 2020 04:54:52

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '06 Nov 2020 12:00'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '07 Nov 2020 11:59'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 4'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:14:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-07T20:56:19', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '0d9701b3-db3a-40e0-97ec-e93099e5ff31' User entered 'Yes (Y)'	System	08 Nov 2020 02:56:30
	System	08 Nov 2020 02:56:30

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:14:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-07T20:56:23', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '0d9701b3-db3a-40e0-97ec-e93099e5ff31' User entered '98.4'	System	08 Nov 2020 02:56:30
	System	08 Nov 2020 02:56:30



US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-07T20:56:26', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '0d9701b3-db3a-40e0-97ec-e93099e5ff31' User entered 'No (N)'	System	08 Nov 2020 02:56:30
	System	08 Nov 2020 02:56:30

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-07T20:56:28', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '0d9701b3-db3a-40e0-97ec-e93099e5ff31' User entered '07 Nov 2020 20:56'	System	08 Nov 2020 02:56:30
	System	08 Nov 2020 02:56:30

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '07 Nov 2020 12:00'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '08 Nov 2020 11:59'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 5'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:14:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-08T23:56:05', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '315c33a6-8cbe-4a5c-a371-0dedf3c5b5e6' User entered 'Yes (Y)'	System	09 Nov 2020 05:56:25
	System	09 Nov 2020 05:56:25

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:14:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-08T23:56:09', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '315c33a6-8cbe-4a5c-a371-0dedf3c5b5e6' User entered '95.1'	System	09 Nov 2020 05:56:25
	System	09 Nov 2020 05:56:25

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-08T23:56:12', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '315c33a6-8cbe-4a5c-a371-0dedf3c5b5e6'	System	09 Nov 2020 05:56:25
User entered 'No (N)'	System	09 Nov 2020 05:56:25



US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-08T23:56:21', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '315c33a6-8cbe-4a5c-a371-0dedf3c5b5e6'	System	09 Nov 2020 05:56:25
User entered '08 Nov 2020 23:56'	System	09 Nov 2020 05:56:25

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '08 Nov 2020 12:00'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '09 Nov 2020 11:59'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 6'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:14:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-09T21:05:58', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '49f715c3-dd72-4652-9235-b596004cb2f4'	System	10 Nov 2020 03:06:42
User entered 'Yes (Y)'	System	10 Nov 2020 03:06:42

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:14:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-09T21:06:36', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '49f715c3-dd72-4652-9235-b596004cb2f4' User entered '98.5'	System	10 Nov 2020 03:06:42
	System	10 Nov 2020 03:06:42

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-09T21:06:38', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '49f715c3-dd72-4652-9235-b596004cb2f4'	System	10 Nov 2020 03:06:42
User entered 'No (N)'	System	10 Nov 2020 03:06:42

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-09T21:06:40', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '49f715c3-dd72-4652-9235-b596004cb2f4' User entered '09 Nov 2020 21:06'	System	10 Nov 2020 03:06:42
	System	10 Nov 2020 03:06:42



US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '09 Nov 2020 12:00'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '10 Nov 2020 11:59'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 7'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:14:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-11T07:40:56', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'a5998037-e476-4fc0-ad28-98c257ea5559' User entered 'Yes (Y)'	System	11 Nov 2020 13:41:18
	System	11 Nov 2020 13:41:18

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:14:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-11T07:41:08', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'a5998037-e476-4fc0-ad28-98c257ea5559' User entered '97.0'	System	11 Nov 2020 13:41:18
	System	11 Nov 2020 13:41:18

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-11T07:41:11', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'a5998037-e476-4fc0-ad28-98c257ea5559' User entered 'No (N)'	System	11 Nov 2020 13:41:18
	System	11 Nov 2020 13:41:18

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-11T07:41:14', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'a5998037-e476-4fc0-ad28-98c257ea5559' User entered '11 Nov 2020 07:41'	System	11 Nov 2020 13:41:18
	System	11 Nov 2020 13:41:18

US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '10 Nov 2020 12:00'	System	04 Nov 2020 16:25:05



US3252624

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '11 Nov 2020 11:59'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T10:54:55', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '0084e8da-a8f8-48ae-9b26-1ba9ac760885'	System	04 Nov 2020 16:55:17
User entered 'Does not interfere with activity (2)'	System	04 Nov 2020 16:55:17

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T10:55:04', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '0084e8da-a8f8-48ae-9b26-1ba9ac760885' User entered 'No (N)'	System	04 Nov 2020 16:55:17
	System	04 Nov 2020 16:55:17

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T10:55:06', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '0084e8da-a8f8-48ae-9b26-1ba9ac760885' User entered 'No (N)'	System	04 Nov 2020 16:55:17
	System	04 Nov 2020 16:55:17

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T10:55:10', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '0084e8da-a8f8-48ae-9b26-1ba9ac760885' User entered 'None (1)'	System	04 Nov 2020 16:55:17
	System	04 Nov 2020 16:55:17

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T10:55:14', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '0084e8da-a8f8-48ae-9b26-1ba9ac760885' User entered '04 Nov 2020 10:55'	System	04 Nov 2020 16:55:17
	System	04 Nov 2020 16:55:17

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '04 Nov 2020 10:43'	System	04 Nov 2020 16:25:05



US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '04 Nov 2020 13:13'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 1, after vaccination (at home)'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:27:42', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9bd9cdb8-8a2d-4ccf-9051-9cebd5269756'	System	05 Nov 2020 04:29:11
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	05 Nov 2020 04:29:11

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:27:44', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9bd9cdb8-8a2d-4ccf-9051-9cebd5269756' User entered 'Yes (Y)'	System	05 Nov 2020 04:29:11
	System	05 Nov 2020 04:29:11

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:28:12', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9bd9cdb8-8a2d-4ccf-9051-9cebd5269756' User entered '20'	System	05 Nov 2020 04:29:11
	System	05 Nov 2020 04:29:11

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:28:21', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9bd9cdb8-8a2d-4ccf-9051-9cebd5269756' User entered 'Yes (Y)'	System	05 Nov 2020 04:29:11
	System	05 Nov 2020 04:29:11

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:28:26', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9bd9cdb8-8a2d-4ccf-9051-9cebd5269756' User entered '20'	System	05 Nov 2020 04:29:11
	System	05 Nov 2020 04:29:11

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:29:05', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9bd9cdb8-8a2d-4ccf-9051-9cebd5269756' User entered 'None (1)'	System	05 Nov 2020 04:29:11
	System	05 Nov 2020 04:29:11



US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:29:08', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '9bd9cdb8-8a2d-4ccf-9051-9cebd5269756' User entered '04 Nov 2020 22:29'	System	05 Nov 2020 04:29:11
	System	05 Nov 2020 04:29:11

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '04 Nov 2020 14:08'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '05 Nov 2020 11:59'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 2'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-05T21:54:21', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '3f5a4561-435b-434f-bfde-98d34361a371'	System	06 Nov 2020 03:55:14
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		06 Nov 2020 03:55:14

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-05T21:54:25', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '3f5a4561-435b-434f-bfde-98d34361a371' User entered 'Yes (Y)'	System	06 Nov 2020 03:55:14
	System	06 Nov 2020 03:55:14

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-05T21:54:45', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '3f5a4561-435b-434f-bfde-98d34361a371' User entered '40'	System	06 Nov 2020 03:55:14
	System	06 Nov 2020 03:55:14

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-05T21:54:48', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '3f5a4561-435b-434f-bfde-98d34361a371' User entered 'Yes (Y)'	System	06 Nov 2020 03:55:14
	System	06 Nov 2020 03:55:14



US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-05T21:54:51', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '3f5a4561-435b-434f-bfde-98d34361a371' User entered '40'	System	06 Nov 2020 03:55:14
	System	06 Nov 2020 03:55:14

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-05T21:55:07', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '3f5a4561-435b-434f-bfde-98d34361a371' User entered 'None (1)'	System	06 Nov 2020 03:55:14
	System	06 Nov 2020 03:55:14

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-05T21:55:11', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '3f5a4561-435b-434f-bfde-98d34361a371' User entered '05 Nov 2020 21:55'	System	06 Nov 2020 03:55:14
	System	06 Nov 2020 03:55:14

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '05 Nov 2020 12:00'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '06 Nov 2020 11:59'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 3'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-06T22:55:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'bb570e7c-3596-4aab-ac1c-630474272054'	System	07 Nov 2020 04:56:08
User entered 'Does not interfere with activity (2)'	System	07 Nov 2020 04:56:08

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-06T22:55:36', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'bb570e7c-3596-4aab-ac1c-630474272054'	System	07 Nov 2020 04:56:08
User entered 'Yes (Y)'	System	07 Nov 2020 04:56:08



US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-06T22:55:50', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'bb570e7c-3596-4aab-ac1c-630474272054' User entered '40'	System	07 Nov 2020 04:56:08
	System	07 Nov 2020 04:56:08

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-06T22:55:53', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'bb570e7c-3596-4aab-ac1c-630474272054' User entered 'Yes (Y)'	System	07 Nov 2020 04:56:08
	System	07 Nov 2020 04:56:08

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-06T22:55:57', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'bb570e7c-3596-4aab-ac1c-630474272054' User entered '40'	System	07 Nov 2020 04:56:08
	System	07 Nov 2020 04:56:08

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-06T22:56:03', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'bb570e7c-3596-4aab-ac1c-630474272054' User entered 'None (1)'	System	07 Nov 2020 04:56:08
	System	07 Nov 2020 04:56:08

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-06T22:56:06', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'bb570e7c-3596-4aab-ac1c-630474272054' User entered '06 Nov 2020 22:56'	System	07 Nov 2020 04:56:08
	System	07 Nov 2020 04:56:08

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '06 Nov 2020 12:00'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '07 Nov 2020 11:59'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 4'	System	04 Nov 2020 16:25:05



US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-07T20:56:42', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '3195e39c-9dd4-437d-82aa-b1f058338f07'	System	08 Nov 2020 02:57:36
User entered 'None (1)'	System	08 Nov 2020 02:57:36

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-07T20:57:13', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '3195e39c-9dd4-437d-82aa-b1f058338f07' User entered 'No (N)'	System	08 Nov 2020 02:57:36
	System	08 Nov 2020 02:57:36

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-07T20:57:15', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '3195e39c-9dd4-437d-82aa-b1f058338f07' User entered 'Yes (Y)'	System	08 Nov 2020 02:57:36
	System	08 Nov 2020 02:57:36

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-07T20:57:22', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '3195e39c-9dd4-437d-82aa-b1f058338f07' User entered '20'	System	08 Nov 2020 02:57:36
	System	08 Nov 2020 02:57:36

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-07T20:57:30', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '3195e39c-9dd4-437d-82aa-b1f058338f07' User entered 'None (1)'	System	08 Nov 2020 02:57:36
	System	08 Nov 2020 02:57:36

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-07T20:57:32', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '3195e39c-9dd4-437d-82aa-b1f058338f07' User entered '07 Nov 2020 20:57'	System	08 Nov 2020 02:57:36
	System	08 Nov 2020 02:57:36

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '07 Nov 2020 12:00'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '08 Nov 2020 11:59'	System	04 Nov 2020 16:25:05



US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 5'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-08T23:56:26', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '03086baf-2175-4df2-b42f-07b43fe277c2'	System	09 Nov 2020 05:56:41
User entered 'None (1)'	System	09 Nov 2020 05:56:41

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-08T23:56:29', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '03086baf-2175-4df2-b42f-07b43fe277c2'	System	09 Nov 2020 05:56:41
User entered 'No (N)'	System	09 Nov 2020 05:56:41

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-08T23:56:31', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '03086baf-2175-4df2-b42f-07b43fe277c2'	System	09 Nov 2020 05:56:41
User entered 'No (N)'	System	09 Nov 2020 05:56:41

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-08T23:56:36', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '03086baf-2175-4df2-b42f-07b43fe277c2'	System	09 Nov 2020 05:56:41
User entered 'None (1)'	System	09 Nov 2020 05:56:41

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-08T23:56:39', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '03086baf-2175-4df2-b42f-07b43fe277c2'	System	09 Nov 2020 05:56:41
User entered '08 Nov 2020 23:56'	System	09 Nov 2020 05:56:41

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '08 Nov 2020 12:00'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '09 Nov 2020 11:59'	System	04 Nov 2020 16:25:05



US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 6'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-09T21:05:14', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'b3a88981-4325-4d9f-b353-8b74518d45e8' User entered 'None (1)'	System	10 Nov 2020 03:05:41
	System	10 Nov 2020 03:05:41

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:14:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-09T21:05:17', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'b3a88981-4325-4d9f-b353-8b74518d45e8' User entered 'No (N)'	System	10 Nov 2020 03:05:41
	System	10 Nov 2020 03:05:41

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-09T21:05:32', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'b3a88981-4325-4d9f-b353-8b74518d45e8' User entered 'No (N)'	System	10 Nov 2020 03:05:41
	System	10 Nov 2020 03:05:41

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-09T21:05:33', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'b3a88981-4325-4d9f-b353-8b74518d45e8' User entered 'None (1)'	System	10 Nov 2020 03:05:41
	System	10 Nov 2020 03:05:41

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-09T21:05:36', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'b3a88981-4325-4d9f-b353-8b74518d45e8' User entered '09 Nov 2020 21:05'	System	10 Nov 2020 03:05:41
	System	10 Nov 2020 03:05:41

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '09 Nov 2020 12:00'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '10 Nov 2020 11:59'	System	04 Nov 2020 16:25:05



US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 7'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-11T07:41:19', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '85d26ab0-7131-415e-9abd-6e60616c248a' User entered 'None (1)'	System	11 Nov 2020 13:41:37
	System	11 Nov 2020 13:41:37

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:14:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-11T07:41:22', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '85d26ab0-7131-415e-9abd-6e60616c248a' User entered 'No (N)'	System	11 Nov 2020 13:41:37
	System	11 Nov 2020 13:41:37

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-11T07:41:24', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '85d26ab0-7131-415e-9abd-6e60616c248a' User entered 'No (N)'	System	11 Nov 2020 13:41:37
	System	11 Nov 2020 13:41:37

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:14:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-11T07:41:29', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '85d26ab0-7131-415e-9abd-6e60616c248a' User entered 'None (1)'	System	11 Nov 2020 13:41:37
	System	11 Nov 2020 13:41:37

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:14:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-11T07:41:32', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '85d26ab0-7131-415e-9abd-6e60616c248a' User entered '11 Nov 2020 07:41'	System	11 Nov 2020 13:41:37
	System	11 Nov 2020 13:41:37

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '10 Nov 2020 12:00'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '11 Nov 2020 11:59'	System	04 Nov 2020 16:25:05



US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T10:55:18', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '1ade1dfc-79a1-43ce-9c24-69e52939c77e' User entered 'None (0)'	System	04 Nov 2020 16:55:37
	System	04 Nov 2020 16:55:37

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T10:55:20', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '1ade1dfc-79a1-43ce-9c24-69e52939c77e' User entered 'None (0)'	System	04 Nov 2020 16:55:37
	System	04 Nov 2020 16:55:37

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T10:55:23', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '1ade1dfc-79a1-43ce-9c24-69e52939c77e' User entered 'None (0)'	System	04 Nov 2020 16:55:37
	System	04 Nov 2020 16:55:37

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T10:55:25', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '1ade1dfc-79a1-43ce-9c24-69e52939c77e' User entered 'None (0)'	System	04 Nov 2020 16:55:37
	System	04 Nov 2020 16:55:37

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T10:55:26', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '1ade1dfc-79a1-43ce-9c24-69e52939c77e' User entered 'None (0)'	System	04 Nov 2020 16:55:37
	System	04 Nov 2020 16:55:37

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T10:55:28', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '1ade1dfc-79a1-43ce-9c24-69e52939c77e' User entered 'None (0)'	System	04 Nov 2020 16:55:37
	System	04 Nov 2020 16:55:37

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

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)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T10:55:30', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '1ade1dfc-79a1-43ce-9c24-69e52939c77e' User entered 'No (N)'	System	04 Nov 2020 16:55:37
	System	04 Nov 2020 16:55:37



US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T10:55:34', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '1ade1dfc-79a1-43ce-9c24-69e52939c77e' User entered '04 Nov 2020 10:55'	System	04 Nov 2020 16:55:37
	System	04 Nov 2020 16:55:37

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '04 Nov 2020 10:43'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '04 Nov 2020 13:13'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 1, after vaccination (at home)'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:29:13', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '0f614016-6b6e-439a-a432-826cdefe732a' User entered 'None (0)'	System	05 Nov 2020 04:29:43
	System	05 Nov 2020 04:29:43

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:29:19', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '0f614016-6b6e-439a-a432-826cdefe732a'	System	05 Nov 2020 04:29:43
User entered 'No interference with activity (1)'	System	05 Nov 2020 04:29:43

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:29:25', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '0f614016-6b6e-439a-a432-826cdefe732a' User entered 'Some interference with activity (2)'	System	05 Nov 2020 04:29:43
	System	05 Nov 2020 04:29:43

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:29:29', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '0f614016-6b6e-439a-a432-826cdefe732a' User entered 'Some interference with activity (2)'	System	05 Nov 2020 04:29:43
	System	05 Nov 2020 04:29:43



US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:29:31', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '0f614016-6b6e-439a-a432-826cdefe732a' User entered 'None (0)'	System	05 Nov 2020 04:29:43
	System	05 Nov 2020 04:29:43

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:29:33', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '0f614016-6b6e-439a-a432-826cdefe732a' User entered 'None (0)'	System	05 Nov 2020 04:29:43
	System	05 Nov 2020 04:29:43

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

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)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:29:35', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '0f614016-6b6e-439a-a432-826cdefe732a' User entered 'No (N)'	System	05 Nov 2020 04:29:43
	System	05 Nov 2020 04:29:43

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-04T22:29:38', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '0f614016-6b6e-439a-a432-826cdefe732a' User entered '04 Nov 2020 22:29'	System	05 Nov 2020 04:29:43
	System	05 Nov 2020 04:29:43

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '04 Nov 2020 14:08'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '05 Nov 2020 11:59'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 2'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-05T21:55:18', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '919a8cb7-caf8-4d43-b793-f6afe583f0ad' User entered 'None (0)'	System	06 Nov 2020 03:55:46
	System	06 Nov 2020 03:55:46



US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-05T21:55:23', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '919a8cb7-caf8-4d43-b793-f6afe583f0ad' User entered 'Significant; prevents daily activity (3)'	System	06 Nov 2020 03:55:46
	System	06 Nov 2020 03:55:46

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-05T21:55:26', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '919a8cb7-caf8-4d43-b793-f6afe583f0ad' User entered 'Significant; prevents daily activity (3)'	System	06 Nov 2020 03:55:46
	System	06 Nov 2020 03:55:46

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-05T21:55:29', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '919a8cb7-caf8-4d43-b793-f6afe583f0ad' User entered 'Significant; prevents daily activity (3)'	System	06 Nov 2020 03:55:46
	System	06 Nov 2020 03:55:46

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-05T21:55:34', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '919a8cb7-caf8-4d43-b793-f6afe583f0ad' User entered 'None (0)'	System	06 Nov 2020 03:55:46
	System	06 Nov 2020 03:55:46

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-05T21:55:37', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '919a8cb7-caf8-4d43-b793-f6afe583f0ad' User entered 'None (0)'	System	06 Nov 2020 03:55:46
	System	06 Nov 2020 03:55:46

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

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)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-05T21:55:41', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '919a8cb7-caf8-4d43-b793-f6afe583f0ad' User entered 'No (N)'	System	06 Nov 2020 03:55:46
	System	06 Nov 2020 03:55:46

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-05T21:55:44', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '919a8cb7-caf8-4d43-b793-f6afe583f0ad' User entered '05 Nov 2020 21:55'	System	06 Nov 2020 03:55:46
	System	06 Nov 2020 03:55:46

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '05 Nov 2020 12:00'	System	04 Nov 2020 16:25:05



**US3252624**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:14:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '06 Nov 2020 11:59'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 3'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-06T22:56:09', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e6089c3b-2f0b-4955-89a7-b848c049633f' User entered 'None (0)'	System	07 Nov 2020 04:56:29
	System	07 Nov 2020 04:56:29

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-06T22:56:11', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e6089c3b-2f0b-4955-89a7-b848c049633f' User entered 'None (0)'	System	07 Nov 2020 04:56:29
	System	07 Nov 2020 04:56:29

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-06T22:56:12', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e6089c3b-2f0b-4955-89a7-b848c049633f' User entered 'None (0)'	System	07 Nov 2020 04:56:29
	System	07 Nov 2020 04:56:29

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-06T22:56:14', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e6089c3b-2f0b-4955-89a7-b848c049633f' User entered 'None (0)'	System	07 Nov 2020 04:56:29
	System	07 Nov 2020 04:56:29

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-06T22:56:15', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e6089c3b-2f0b-4955-89a7-b848c049633f' User entered 'None (0)'	System	07 Nov 2020 04:56:29
	System	07 Nov 2020 04:56:29

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-06T22:56:17', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e6089c3b-2f0b-4955-89a7-b848c049633f' User entered 'None (0)'	System	07 Nov 2020 04:56:29
	System	07 Nov 2020 04:56:29



US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

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)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-06T22:56:20', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e6089c3b-2f0b-4955-89a7-b848c049633f' User entered 'No (N)'	System	07 Nov 2020 04:56:29
	System	07 Nov 2020 04:56:29

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-06T22:56:26', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e6089c3b-2f0b-4955-89a7-b848c049633f' User entered '06 Nov 2020 22:56'	System	07 Nov 2020 04:56:29
	System	07 Nov 2020 04:56:29

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '06 Nov 2020 12:00'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '07 Nov 2020 11:59'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 4'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-07T20:55:48', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'c316b523-f137-4acb-9dd3-2cad202b3db8' User entered 'None (0)'	System	08 Nov 2020 02:56:16
	System	08 Nov 2020 02:56:16

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-07T20:55:54', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'c316b523-f137-4acb-9dd3-2cad202b3db8' User entered 'None (0)'	System	08 Nov 2020 02:56:16
	System	08 Nov 2020 02:56:16

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-07T20:55:56', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'c316b523-f137-4acb-9dd3-2cad202b3db8' User entered 'None (0)'	System	08 Nov 2020 02:56:16
	System	08 Nov 2020 02:56:16



US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-07T20:55:59', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'c316b523-f137-4acb-9dd3-2cad202b3db8' User entered 'None (0)'	System	08 Nov 2020 02:56:16
	System	08 Nov 2020 02:56:16

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-07T20:56:01', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'c316b523-f137-4acb-9dd3-2cad202b3db8' User entered 'None (0)'	System	08 Nov 2020 02:56:16
	System	08 Nov 2020 02:56:16

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-07T20:56:03', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'c316b523-f137-4acb-9dd3-2cad202b3db8' User entered 'None (0)'	System	08 Nov 2020 02:56:16
	System	08 Nov 2020 02:56:16

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

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)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-07T20:56:08', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'c316b523-f137-4acb-9dd3-2cad202b3db8' User entered 'No (N)'	System	08 Nov 2020 02:56:16
	System	08 Nov 2020 02:56:16

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-07T20:56:13', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'c316b523-f137-4acb-9dd3-2cad202b3db8' User entered '07 Nov 2020 20:56'	System	08 Nov 2020 02:56:16
	System	08 Nov 2020 02:56:16

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '07 Nov 2020 12:00'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '08 Nov 2020 11:59'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 5'	System	04 Nov 2020 16:25:05



US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-08T23:56:42', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8e3cdeb7-57cf-420c-b556-c86e44e72440' User entered 'None (0)'	System	09 Nov 2020 05:57:01
	System	09 Nov 2020 05:57:01

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-08T23:56:44', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8e3cdeb7-57cf-420c-b556-c86e44e72440' User entered 'None (0)'	System	09 Nov 2020 05:57:01
	System	09 Nov 2020 05:57:01

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-08T23:56:46', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8e3cdeb7-57cf-420c-b556-c86e44e72440' User entered 'None (0)'	System	09 Nov 2020 05:57:01
	System	09 Nov 2020 05:57:01

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-08T23:56:47', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8e3cdeb7-57cf-420c-b556-c86e44e72440' User entered 'None (0)'	System	09 Nov 2020 05:57:01
	System	09 Nov 2020 05:57:01

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-08T23:56:50', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8e3cdeb7-57cf-420c-b556-c86e44e72440' User entered 'None (0)'	System	09 Nov 2020 05:57:01
	System	09 Nov 2020 05:57:01

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-08T23:56:51', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8e3cdeb7-57cf-420c-b556-c86e44e72440' User entered 'None (0)'	System	09 Nov 2020 05:57:01
	System	09 Nov 2020 05:57:01

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

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)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-08T23:56:53', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8e3cdeb7-57cf-420c-b556-c86e44e72440' User entered 'No (N)'	System	09 Nov 2020 05:57:01
	System	09 Nov 2020 05:57:01

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-08T23:56:55', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8e3cdeb7-57cf-420c-b556-c86e44e72440' User entered '08 Nov 2020 23:56'	System	09 Nov 2020 05:57:01
	System	09 Nov 2020 05:57:01



US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '08 Nov 2020 12:00'	System	04 Nov 2020 16:25:05

**US3252624**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:14:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '09 Nov 2020 11:59'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 6'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-09T21:05:39', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e4e4d734-95ae-4798-b83b-3adefb2d4df'	System	10 Nov 2020 03:05:51
User entered 'None (0)'	System	10 Nov 2020 03:05:51

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-09T21:05:40', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e4e4d734-95ae-4798-b83b-3adefb2d4df' User entered 'None (0)'	System	10 Nov 2020 03:05:51
	System	10 Nov 2020 03:05:51

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-09T21:05:41', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e4e4d734-95ae-4798-b83b-3adefb2d4df' User entered 'None (0)'	System	10 Nov 2020 03:05:51
	System	10 Nov 2020 03:05:51

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-09T21:05:42', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e4e4d734-95ae-4798-b83b-3adefb2d4df' User entered 'None (0)'	System	10 Nov 2020 03:05:51
	System	10 Nov 2020 03:05:51

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-09T21:05:43', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e4e4d734-95ae-4798-b83b-3adefb2d4df' User entered 'None (0)'	System	10 Nov 2020 03:05:51
	System	10 Nov 2020 03:05:51



US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-09T21:05:44', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e4e4d734-95ae-4798-b83b-3adefb2d4df' User entered 'None (0)'	System	10 Nov 2020 03:05:51
	System	10 Nov 2020 03:05:51

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

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)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-09T21:05:46', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e4e4d734-95ae-4798-b83b-3adefb2d4df' User entered 'No (N)'	System	10 Nov 2020 03:05:51
	System	10 Nov 2020 03:05:51

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-09T21:05:48', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e4e4d734-95ae-4798-b83b-3adefb2d4df' User entered '09 Nov 2020 21:05'	System	10 Nov 2020 03:05:51
	System	10 Nov 2020 03:05:51

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '09 Nov 2020 12:00'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '10 Nov 2020 11:59'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
Data entry locked.	System	04 Nov 2020 16:25:05
User entered 'Day 7'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-11T07:41:35', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '5019ffee-6813-4e15-974e-cd3fe9bf0bd3' User entered 'None (0)'	System	11 Nov 2020 13:41:50
	System	11 Nov 2020 13:41:50

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-11T07:41:37', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '5019ffee-6813-4e15-974e-cd3fe9bf0bd3' User entered 'None (0)'	System	11 Nov 2020 13:41:50
	System	11 Nov 2020 13:41:50



US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-11T07:41:38', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '5019ffee-6813-4e15-974e-cd3fe9bf0bd3' User entered 'None (0)'	System	11 Nov 2020 13:41:50
	System	11 Nov 2020 13:41:50

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-11T07:41:40', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '5019ffee-6813-4e15-974e-cd3fe9bf0bd3' User entered 'None (0)'	System	11 Nov 2020 13:41:50
	System	11 Nov 2020 13:41:50

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-11T07:41:41', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '5019ffee-6813-4e15-974e-cd3fe9bf0bd3' User entered 'None (0)'	System	11 Nov 2020 13:41:50
	System	11 Nov 2020 13:41:50

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-11T07:41:43', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '5019ffee-6813-4e15-974e-cd3fe9bf0bd3' User entered 'None (0)'	System	11 Nov 2020 13:41:50
	System	11 Nov 2020 13:41:50

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

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)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-11T07:41:45', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '5019ffee-6813-4e15-974e-cd3fe9bf0bd3' User entered 'No (N)'	System	11 Nov 2020 13:41:50
	System	11 Nov 2020 13:41:50

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-11-11T07:41:47', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '5019ffee-6813-4e15-974e-cd3fe9bf0bd3' User entered '11 Nov 2020 07:41'	System	11 Nov 2020 13:41:50
	System	11 Nov 2020 13:41:50

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '10 Nov 2020 12:00'	System	04 Nov 2020 16:25:05

US3252624

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:14:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:24:37
User entered '11 Nov 2020 11:59'	System	04 Nov 2020 16:25:05



**US3252624**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	19 Nov 2020 03:50:26
	(b) (4)	

**US3252624**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered '11 Nov 2020'	Shannon Moyer (b) (4)	19 Nov 2020 03:50:26
	(b) (4)	

US3252624

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Contact Not Made (CONTACT NOT MADE)'	Shannon Moyer (b) (4)	19 Nov 2020 03:50:26
	(b) (4)	

US3252624

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User closed query 'The Contact Status is 'CONTACT System NOT MADE'; however, Comments have not been provided.		19 Nov 2020 03:52:41
Please review and reconcile.' (Site from System).		
User entered 'LEFT VOICE MAIL' reason for change: Data Entry Error	Shannon Moyer (b) (4)	19 Nov 2020 03:52:41
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	(b) (4)	
Please review and reconcile.' (Site from System).	System	19 Nov 2020 03:50:26
User entered empty.	Shannon Moyer (b) (4)	19 Nov 2020 03:50:26
	(b) (4)	

**US3252624**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	19 Nov 2020 03:52:48
	(b) (4)	

**US3252624**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:14:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'I'	System	19 Nov 2020 03:52:48

**US3252624**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	19 Nov 2020 03:52:58
	(b) (4)	

**US3252624**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered '18 Nov 2020'	Shannon Moyer (b) (4)	19 Nov 2020 03:52:58
	(b) (4)	



US3252624

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	19 Nov 2020 03:52:58
	(b) (4)	

US3252624

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered empty.	Shannon Moyer (b) (4)	19 Nov 2020 03:52:58
	(b) (4)	

US3252624

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	19 Nov 2020 03:53:05
	(b) (4)	

**US3252624**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:14:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'I'	System	19 Nov 2020 03:53:05

**US3252624**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	26 Nov 2020 03:13:18
	(b) (4)	

**US3252624**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered '25 Nov 2020'	Shannon Moyer (b) (4)	26 Nov 2020 03:13:18
	(b) (4)	

**US3252624**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4)	26 Nov 2020 03:13:18
	(b) (4)	

US3252624

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered empty.	Shannon Moyer (b) (4)	26 Nov 2020 03:13:18
	(b) (4)	



US3252624

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:53:32
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	26 Nov 2020 03:13:24
	(b) (4)	

**US3252624**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:14:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'I'	System	26 Nov 2020 03:13:24

**US3252624**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:14:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	03 Dec 2020 02:26:47
	(b) (4)	

US3252624

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '2 Dec 2020'	Shannon Moyer (b) (4)	03 Dec 2020 02:26:47
	(b) (4)	

US3252624

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4)	03 Dec 2020 02:26:47
	(b) (4)	

**US3252624**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:14:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'VISIT3'	System	03 Dec 2020 02:26:47

US3252624

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	03 Dec 2020 02:27:35
	(b) (4)	

US3252624

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '2 Dec 2020'	Shannon Moyer (b) (4)	03 Dec 2020 02:27:35
	(b) (4)	



US3252624

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '09:49'	Shannon Moyer (b) (4)	03 Dec 2020 02:27:35
	(b) (4)	

**US3252624**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered '2 Dec 2020 09:49'	System	03 Dec 2020 02:27:35

US3252624

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '98.6' F	Shannon Moyer (b) (4)	03 Dec 2020 02:27:35
	(b) (4)	

US3252624

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	03 Dec 2020 02:27:35
	(b) (4)	

US3252624

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	Shannon Moyer (b) (4)	03 Dec 2020 02:27:35
	(b) (4)	

US3252624

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '80'	Shannon Moyer (b) (4)	03 Dec 2020 02:27:35
	(b) (4)	

**US3252624**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:14:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'bpm'	System	03 Dec 2020 02:27:35

US3252624

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '16'	Shannon Moyer (b) (4)	03 Dec 2020 02:27:35
	(b) (4)	



US3252624

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'breaths/min'	System	03 Dec 2020 02:27:35

US3252624

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '125'	Shannon Moyer (b) (4)	03 Dec 2020 02:27:35
	(b) (4)	

US3252624

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'mmHg'	System	03 Dec 2020 02:27:35

US3252624

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '82'	Shannon Moyer (b) (4)	03 Dec 2020 02:27:35
	(b) (4)	

US3252624

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'mmHg'	System	03 Dec 2020 02:27:35

US3252624

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52

US3252624

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:14:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52

US3252624

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'No (N)'	Shannon Moyer (b) (4)	03 Dec 2020 02:27:42
	(b) (4)	



US3252624

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:14:24

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered empty.	Shannon Moyer (b) (4)	03 Dec 2020 02:27:42
	(b) (4)	

US3252624

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	03 Dec 2020 02:27:57
	(b) (4)	

US3252624

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '2 Dec 2020'	Shannon Moyer (b) (4)	03 Dec 2020 02:27:57
	(b) (4)	

US3252624

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered '10:11'	Shannon Moyer (b) (4)	03 Dec 2020 02:27:57
	(b) (4)	

**US3252624**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered '2 Dec 2020 10:11'	System	03 Dec 2020 02:27:57

US3252624

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 03:54:01
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	03 Dec 2020 02:28:05
	(b) (4)	

**US3252624**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:14:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'I'	System	03 Dec 2020 02:28:05

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:46:52



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-12-04T16:18:56', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '2cc5fddc-ae20-4139-bb13-945a283feb9d' User entered 'No (N)'	System	04 Dec 2020 22:19:18
	System	04 Dec 2020 22:19:18

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-12-04T16:19:06', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '2cc5fddc-ae20-4139-bb13-945a283feb9d'	System	04 Dec 2020 22:19:18
User entered 'No (N)'	System	04 Dec 2020 22:19:18

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-12-04T16:19:12', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '2cc5fddc-ae20-4139-bb13-945a283feb9d' User entered '04 Dec 2020 16:19:12'	System	04 Dec 2020 22:19:18
	System	04 Dec 2020 22:19:18

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-12-09T00:18:36', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'b77b4edb-415f-4450-bee5-c621b2575d5c' User entered 'No (N)'	System	09 Dec 2020 06:18:44
	System	09 Dec 2020 06:18:44

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-12-09T00:18:38', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'b77b4edb-415f-4450-bee5-c621b2575d5c'	System	09 Dec 2020 06:18:44
User entered 'No (N)'	System	09 Dec 2020 06:18:44



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-12-09T00:18:42', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'b77b4edb-415f-4450-bee5-c621b2575d5c' User entered '09 Dec 2020 00:18:42'	System	09 Dec 2020 06:18:44
	System	09 Dec 2020 06:18:44

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-12-16T07:45:44', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '6ef09891-f2ea-420e-ae93-85f9bb26b2da' User entered 'No (N)'	System	16 Dec 2020 13:45:57
	System	16 Dec 2020 13:45:57

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-12-16T07:45:47', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '6ef09891-f2ea-420e-ae93-85f9bb26b2da'	System	16 Dec 2020 13:45:57
User entered 'No (N)'	System	16 Dec 2020 13:45:57

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-12-16T07:45:53', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '6ef09891-f2ea-420e-ae93-85f9bb26b2da' User entered '16 Dec 2020 07:45:53'	System	16 Dec 2020 13:45:57
	System	16 Dec 2020 13:45:57

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 11:46:52



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-12-23T08:19:20', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '44fe7d5b-acbb-4652-902e-1b39ed7df23d' User entered 'Yes (Y)'	System	23 Dec 2020 14:20:20
	System	23 Dec 2020 14:20:20

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-12-23T08:19:28', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '44fe7d5b-acbb-4652-902e-1b39ed7df23d' User entered 'No (N)'	System	23 Dec 2020 14:20:20
	System	23 Dec 2020 14:20:20

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-12-23T08:19:33', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '44fe7d5b-acbb-4652-902e-1b39ed7df23d' User entered 'No (N)'	System	23 Dec 2020 14:20:20
	System	23 Dec 2020 14:20:20

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-12-23T08:20:13', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '44fe7d5b-acbb-4652-902e-1b39ed7df23d' User entered 'No (N)'	System	23 Dec 2020 14:20:20
	System	23 Dec 2020 14:20:20

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-12-23T08:20:17', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '44fe7d5b-acbb-4652-902e-1b39ed7df23d' User entered '23 Dec 2020 08:20:17'	System	23 Dec 2020 14:20:20
	System	23 Dec 2020 14:20:20

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 11:46:52



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-12-30T05:16:25', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8c0812be-a641-4299-bea4-705e8031ddb9' User entered 'No (N)'	System	30 Dec 2020 11:16:37
	System	30 Dec 2020 11:16:37

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-12-30T05:16:28', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8c0812be-a641-4299-bea4-705e8031ddb9' User entered 'No (N)'	System	30 Dec 2020 11:16:37

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2020-12-30T05:16:35', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '8c0812be-a641-4299-bea4-705e8031ddb9' User entered '30 Dec 2020 05:16:35'	System	30 Dec 2020 11:16:37
	System	30 Dec 2020 11:16:37

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:46:52



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-01-08T23:07:58', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '4f4438f3-552d-4975-88c6-57a14fe0628f' User entered 'No (N)'	System	09 Jan 2021 05:08:12
	System	09 Jan 2021 05:08:12

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-01-08T23:08:05', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '4f4438f3-552d-4975-88c6-57a14fe0628f' User entered 'No (N)'	System	09 Jan 2021 05:08:12

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-01-08T23:08:07', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '4f4438f3-552d-4975-88c6-57a14fe0628f' User entered '08 Jan 2021 23:08:07'	System	09 Jan 2021 05:08:12
	System	09 Jan 2021 05:08:12

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-01-13T01:23:22', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'd3f6a75e-1e37-4451-a4e7-555a358d5b22'	System	13 Jan 2021 07:23:35
User entered 'No (N)'	System	13 Jan 2021 07:23:35

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-01-13T01:23:25', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'd3f6a75e-1e37-4451-a4e7-555a358d5b22'	System	13 Jan 2021 07:23:35
User entered 'No (N)'	System	13 Jan 2021 07:23:35



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-01-13T01:23:28', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'd3f6a75e-1e37-4451-a4e7-555a358d5b22' User entered '13 Jan 2021 01:23:28'	System	13 Jan 2021 07:23:35
	System	13 Jan 2021 07:23:35

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:46:52

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-01-20T18:47:38', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'b0c379f2-2533-494b-b610-9a7e09a37d63' User entered 'No (N)'	System	21 Jan 2021 00:47:46
	System	21 Jan 2021 00:47:46

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-01-20T18:47:40', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'b0c379f2-2533-494b-b610-9a7e09a37d63'	System	21 Jan 2021 00:47:46
User entered 'No (N)'	System	21 Jan 2021 00:47:46

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-01-20T18:47:43', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'b0c379f2-2533-494b-b610-9a7e09a37d63' User entered '20 Jan 2021 18:47:43'	System	21 Jan 2021 00:47:46

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 11:46:52



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-01-29T12:41:39', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'b6cd0790-4a56-46db-a81d-6273a20b3dd8'	System	29 Jan 2021 18:41:48
User entered 'No (N)'	System	29 Jan 2021 18:41:48

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-01-29T12:41:42', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'b6cd0790-4a56-46db-a81d-6273a20b3dd8'	System	29 Jan 2021 18:41:48
User entered 'No (N)'	System	29 Jan 2021 18:41:48

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-01-29T12:41:45', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'b6cd0790-4a56-46db-a81d-6273a20b3dd8' User entered '29 Jan 2021 12:41:45'	System	29 Jan 2021 18:41:48

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:46:52



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-02-07T11:59:21', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'c8ef4c86-cc29-41d1-b8ec-82b554cd2707'	System	07 Feb 2021 17:59:28
User entered 'No (N)'	System	07 Feb 2021 17:59:28

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-02-07T11:59:24', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'c8ef4c86-cc29-41d1-b8ec-82b554cd2707'	System	07 Feb 2021 17:59:28
User entered 'No (N)'	System	07 Feb 2021 17:59:28

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-02-07T11:59:26', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'c8ef4c86-cc29-41d1-b8ec-82b554cd2707'	System	07 Feb 2021 17:59:28
User entered '07 Feb 2021 11:59:26'	System	07 Feb 2021 17:59:28

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-02-10T00:01:40', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '73131b7a-1f19-405e-83f5-9cf9ee4d817e' User entered 'No (N)'	System	10 Feb 2021 06:02:29
	System	10 Feb 2021 06:02:29

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-02-10T00:02:22', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '73131b7a-1f19-405e-83f5-9cf9ee4d817e' User entered 'No (N)'	System	10 Feb 2021 06:02:29



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-02-10T00:02:26', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '73131b7a-1f19-405e-83f5-9cf9ee4d817e' User entered '10 Feb 2021 00:02:26'	System	10 Feb 2021 06:02:29
	System	10 Feb 2021 06:02:29

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-02-18T18:22:36', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e487f128-78c0-4a65-b9ce-803d8c448b8e' User entered 'No (N)'	System	19 Feb 2021 00:24:42
	System	19 Feb 2021 00:24:42

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-02-18T18:22:38', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e487f128-78c0-4a65-b9ce-803d8c448b8e' User entered 'No (N)'	System	19 Feb 2021 00:24:42
	System	19 Feb 2021 00:24:42

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-02-18T18:22:41', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'e487f128-78c0-4a65-b9ce-803d8c448b8e' User entered '18 Feb 2021 18:22:41'	System	19 Feb 2021 00:24:42
	System	19 Feb 2021 00:24:42

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 11:46:52



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-02-24T00:07:36-06:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'ab042cf9-5129-4515-bfca-5059d31f3016'	System	24 Feb 2021 06:07:44
User entered 'No (N)'	System	24 Feb 2021 06:07:44

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-02-24T00:07:38-06:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'ab042cf9-5129-4515-bfca-5059d31f3016'	System	24 Feb 2021 06:07:44
User entered 'No (N)'	System	24 Feb 2021 06:07:44

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-02-24T00:07:40-06:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'ab042cf9-5129-4515-bfca-5059d31f3016' User entered '24 Feb 2021 06:07:40'	System	24 Feb 2021 06:07:44
	System	24 Feb 2021 06:07:44

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:46:52



US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-03-03T06:50:40-06:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '77e28689-bdf6-4839-a450-f96aa0f13964'	System	03 Mar 2021 12:50:49
User entered 'No (N)'	System	03 Mar 2021 12:50:49

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-03-03T06:50:44-06:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '77e28689-bdf6-4839-a450-f96aa0f13964'	System	03 Mar 2021 12:50:49
User entered 'No (N)'	System	03 Mar 2021 12:50:49

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-03-03T06:50:46-06:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '77e28689-bdf6-4839-a450-f96aa0f13964'	System	03 Mar 2021 12:50:49
User entered '03 Mar 2021 06:50:46'	System	03 Mar 2021 12:50:49

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-03-10T22:05:10-06:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '45308be4-7d23-45cb-899b-bf991bf5dd04'	System	11 Mar 2021 04:05:24
User entered 'No (N)'	System	11 Mar 2021 04:05:24

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-03-10T22:05:17-06:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '45308be4-7d23-45cb-899b-bf991bf5dd04'	System	11 Mar 2021 04:05:24
User entered 'No (N)'	System	11 Mar 2021 04:05:24



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-03-10T22:05:20-06:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '45308be4-7d23-45cb-899b-bf991bf5dd04'	System	11 Mar 2021 04:05:24
User entered '10 Mar 2021 22:05:20'	System	11 Mar 2021 04:05:24

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-03-17T06:34:46-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '3fb28c47-ce0e-4803-9f9b-3729ab748a16'	System	17 Mar 2021 11:35:09
User entered 'No (N)'	System	17 Mar 2021 11:35:09

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-03-17T06:34:58-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '3fb28c47-ce0e-4803-9f9b-3729ab748a16'	System	17 Mar 2021 11:35:09
User entered 'No (N)'	System	17 Mar 2021 11:35:09

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-03-17T06:35:01-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '3fb28c47-ce0e-4803-9f9b-3729ab748a16' User entered '17 Mar 2021 06:35:01'	System	17 Mar 2021 11:35:09
	System	17 Mar 2021 11:35:09

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 11:46:52



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-03-24T21:21:55-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'f5531fae-2ef7-4bbb-88ae-cf3dd7770de0' User entered 'No (N)'	System	25 Mar 2021 02:22:06
	System	25 Mar 2021 02:22:06

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-03-24T21:21:58-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'f5531fae-2ef7-4bbb-88ae-cf3dd7770de0' User entered 'No (N)'	System	25 Mar 2021 02:22:06

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-03-24T21:22:01-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'f5531fae-2ef7-4bbb-88ae-cf3dd7770de0' User entered '24 Mar 2021 21:22:01'	System	25 Mar 2021 02:22:06
	System	25 Mar 2021 02:22:06

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:46:52



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-04-04T12:35:05-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '6f4fd77b-de15-4e9c-bfcf-cdd3da1c6d25'	System	04 Apr 2021 17:35:16
User entered 'No (N)'	System	04 Apr 2021 17:35:16

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-04-04T12:35:11-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '6f4fd77b-de15-4e9c-bfcf-cdd3da1c6d25'	System	04 Apr 2021 17:35:16
User entered 'No (N)'	System	04 Apr 2021 17:35:16

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-04-04T12:35:13-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '6f4fd77b-de15-4e9c-bfcf-cdd3da1c6d25'	System	04 Apr 2021 17:35:16
User entered '04 Apr 2021 12:35:13'	System	04 Apr 2021 17:35:16

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-04-07T12:40:03-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'c20a9107-eb81-4273-9e61-a73d75e8ce28'	System	07 Apr 2021 17:40:11
User entered 'No (N)'	System	07 Apr 2021 17:40:11

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-04-07T12:40:04-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'c20a9107-eb81-4273-9e61-a73d75e8ce28'	System	07 Apr 2021 17:40:11
User entered 'No (N)'	System	07 Apr 2021 17:40:11



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-04-07T12:40:07-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'c20a9107-eb81-4273-9e61-a73d75e8ce28'	System	07 Apr 2021 17:40:11
User entered '07 Apr 2021 12:40:07'	System	07 Apr 2021 17:40:11

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-04-14T00:12:54-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '1fb8201b-21dc-49f5-b36e-37ad74b6dece' User entered 'Yes (Y)'	System	14 Apr 2021 05:13:46
	System	14 Apr 2021 05:13:46

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-04-14T00:13:00-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '1fb8201b-21dc-49f5-b36e-37ad74b6dece' User entered 'No (N)'	System	14 Apr 2021 05:13:46

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-04-14T00:13:08-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '1fb8201b-21dc-49f5-b36e-37ad74b6dece'	System	14 Apr 2021 05:13:46
User entered 'No (N)'	System	14 Apr 2021 05:13:46

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-04-14T00:13:15-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '1fb8201b-21dc-49f5-b36e-37ad74b6dece' User entered 'Yes (Y)'	System	14 Apr 2021 05:13:46
	System	14 Apr 2021 05:13:46



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-04-14T00:13:21-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '1fb8201b-21dc-49f5-b36e-37ad74b6dece'	System	14 Apr 2021 05:13:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Apr 2021 05:13:46

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-04-14T00:13:25-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '1fb8201b-21dc-49f5-b36e-37ad74b6dece' User entered '14 Apr 2021 00:13:25'	System	14 Apr 2021 05:13:46
	System	14 Apr 2021 05:13:46

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-04-21T07:19:29-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '11d8fbb7-23a2-460c-9bb8-ead56bd9a64e' User entered 'No (N)'	System	02 May 2021 17:20:09
	System	02 May 2021 17:20:09

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-04-21T07:19:32-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '11d8fbb7-23a2-460c-9bb8-ead56bd9a64e'	System	02 May 2021 17:20:09
User entered 'No (N)'	System	02 May 2021 17:20:09

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-04-21T07:19:35-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '11d8fbb7-23a2-460c-9bb8-ead56bd9a64e'	System	02 May 2021 17:20:09
User entered '21 Apr 2021 07:19:35'	System	02 May 2021 17:20:09



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-05-02T12:20:05-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'c5a5f2fe-4b6a-4068-b4d5-249f96238958'	System	02 May 2021 17:20:17
User entered 'No (N)'	System	02 May 2021 17:20:17

US3252624

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:14:24

Have you been exposed to someone with 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 (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-05-02T12:20:10-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'c5a5f2fe-4b6a-4068-b4d5-249f96238958'	System	02 May 2021 17:20:17
User entered 'No (N)'	System	02 May 2021 17:20:17

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-05-02T12:20:15-05:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: 'c5a5f2fe-4b6a-4068-b4d5-249f96238958'	System	02 May 2021 17:20:17
User entered '02 May 2021 12:20:15'	System	02 May 2021 17:20:17

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 11:46:52



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 11:46:52



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:46:52



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 11:46:52



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:46:52

**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 11:46:52



**US3252624**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '09 Nov 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '13 Nov 2022 23:59'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '16 Nov 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '20 Nov 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '23 Nov 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '27 Nov 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '30 Nov 2022 00:01'	System	20 Nov 2020 11:46:52



**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '04 Dec 2022 23:59'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '07 Dec 2022 00:01'	System	20 Nov 2020 11:46:52

**US3252624**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:14:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:46:52
Amendment Manager: User entered '11 Dec 2022 23:59'	System	20 Nov 2020 11:46:52

US3252624

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:14:24

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)	25 Apr 2021 02:46:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-03-03T06:50:56-06:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '05717a67-2a8f-4653-a743-cd3e995876b3'	System	03 Mar 2021 12:51:08
User entered 'No (N)'	System	03 Mar 2021 12:51:08

US3252624

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:14:24

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:46:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F0735EFA-A86B-47D5-9DE8-F14A687ABACA)', Time: '2021-03-03T06:51:00-06:00', User OID: 'PatientReportedOutcome (US3252624)', ODM File OID: '05717a67-2a8f-4653-a743-cd3e995876b3' User entered '03 Mar 2021 06:51:00'	System	03 Mar 2021 12:51:08
	System	03 Mar 2021 12:51:08

**US3252624**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:17:03
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	03 Feb 2021 04:46:35

**US3252624**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:17:03
User entered '2 Jan 2021'	Joanna Gurrola Mahoney (b) (4)	03 Feb 2021 04:46:35



US3252624

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:17:03
User entered 'Contact Made (CONTACT MADE)'	Joanna Gurrola Mahoney (b) (4)	03 Feb 2021 04:46:35

US3252624

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:17:03
User entered empty.	Joanna Gurrola Mahoney (b) (4)	03 Feb 2021 04:46:35

US3252624

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:14:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:17:03
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	03 Feb 2021 04:46:39

**US3252624**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:14:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:31:52
User entered 'I'	System	03 Feb 2021 04:46:39

**US3252624**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:17:03
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	03 Feb 2021 04:47:01

**US3252624**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:17:03
User entered '2 Feb 2021'	Joanna Gurrola Mahoney (b) (4)	03 Feb 2021 04:47:01

**US3252624**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:17:03
User entered 'Contact Made (CONTACT MADE)'	Joanna Gurrola Mahoney (b) (4)	03 Feb 2021 04:47:01

**US3252624**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:17:03
User entered empty.	Joanna Gurrola Mahoney (b) (4)	03 Feb 2021 04:47:01



**US3252624**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:14:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:17:03
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	03 Feb 2021 04:47:05

**US3252624**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:14:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:40:41
User entered 'I'	System	03 Feb 2021 04:47:05

**US3252624**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:17:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 03:51:24

**US3252624**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:17:03
User entered '3 Mar 2021'	(b) (4), (b) (6)	04 Mar 2021 03:51:24

**US3252624**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:17:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Mar 2021 03:51:24

**US3252624**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:17:03
User entered empty.	(b) (4), (b) (6)	04 Mar 2021 03:51:24

**US3252624**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:14:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:17:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Mar 2021 03:51:27

**US3252624**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:14:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:40:41
User entered 'I'	System	04 Mar 2021 03:51:27



**US3252624**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 03:52:58

**US3252624**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '2 Apr 2021'	(b) (4), (b) (6)	05 Apr 2021 03:52:58

**US3252624**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:14:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Apr 2021 03:52:58

US3252624

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:14:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 03:52:58

**US3252624**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:14:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:40:41
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 03:53:03

**US3252624**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:14:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:40:41
User entered 'I'	System	05 Apr 2021 03:53:03

US3252624

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 02:36:21

US3252624

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:14:24

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '17 Mar 2021'	(b) (4), (b) (6)	18 Mar 2021 02:36:21



**US3252624**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:14:24**

[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 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	18 Mar 2021 02:36:21

**US3252624**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:14:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered 'UNBLND_DECIDE'	System	18 Mar 2021 02:36:21

US3252624

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:14:24

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '17 Mar 2021'	(b) (4), (b) (6)	18 Mar 2021 02:36:39

**US3252624**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:14:24**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '0'	(b) (4), (b) (6)	18 Mar 2021 02:36:39

**US3252624**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:14:24**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 02:36:39

**US3252624**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:14:24**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	18 Mar 2021 02:36:39

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:14:24

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '17 Mar 2021'	(b) (4), (b) (6)	18 Mar 2021 02:36:39

US3252624

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:14:24

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	18 Mar 2021 02:36:39



**US3252624**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:14:24**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	18 Mar 2021 02:36:39

US3252624

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:14:24

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	18 Mar 2021 02:36:39

US3252624

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:14:24

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'No (N)'	(b) (4), (b) (6)	18 Mar 2021 02:36:39

**US3252624**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:14:24**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered empty.	System	18 Mar 2021 02:36:39

**US3252624**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:14:24**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered empty.	System	18 Mar 2021 02:36:39

US3252624

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:14:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 02:36:50

**US3252624**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:14:24**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '17 Mar 2021'	(b) (4), (b) (6)	18 Mar 2021 02:36:50

**US3252624**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:14:24**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '13:56'	(b) (4), (b) (6)	18 Mar 2021 02:36:50



**US3252624**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:14:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered '17 Mar 2021 13:56'	System	18 Mar 2021 02:36:50

**US3252624**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:14:24**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 02:37:01

**US3252624**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:14:24**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '17 Mar 2021'	(b) (4), (b) (6)	18 Mar 2021 02:37:01

**US3252624**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:14:24**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '13:56'	(b) (4), (b) (6)	18 Mar 2021 02:37:01

**US3252624**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:14:24**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:11:34
User entered '17 Mar 2021 13:56'	System	18 Mar 2021 02:37:01

US3252624

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:14:24

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:54:45
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User closed query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary dose 1, Join Aches Day 8 and Muscle aches Day 8 lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 11:52:36
Query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary dose 1, Join Aches Day 8 and Muscle aches Day 8 lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' answered with 'AE updated' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 05:37:42
Signature has been broken.	Xavier Morales (b) (4)	21 Apr 2021 20:22:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Xavier Morales (b) (4)	21 Apr 2021 20:22:34
User opened query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary dose 1, Join Aches Day 8 and Muscle aches Day 8 lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 04:19:37

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:14:24

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary dose 1, Join Aches Day8 lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' canceled (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 04:18:58
User opened query 'Per CDM : Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary dose 1, Join Aches Day8 lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 04:17:53
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:17:03
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:39:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:24
User entered	System	22 Apr 2021 14:57:15
'USA-US108-2021-mRNA-1273-P301000021'		
User entered 'New'	(b) (4), (b) (6)	22 Apr 2021 14:57:15



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Pneumonia bacterial, LLT: Pneumonia bacterial - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 20:25:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 20:25:31
Data point term sent to Coder	System	21 Apr 2021 20:24:17
User entered 'Bacterial Pneumonia'	Xavier Morales (b) (4)	21 Apr 2021 20:23:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 18:23:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Apr 2021 18:23:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	22 Apr 2021 18:23:20
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 20:23:21
User entered empty.	Xavier Morales (b) (4)	21 Apr 2021 20:23:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 18:23:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Apr 2021 18:23:20
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	22 Apr 2021 18:23:20
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 20:23:21
User entered empty.	Xavier Morales (b) (4)	21 Apr 2021 20:23:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 18:23:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Apr 2021 18:23:20
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	22 Apr 2021 18:23:20
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 20:23:21
User entered empty.	Xavier Morales (b) (4)	21 Apr 2021 20:23:21

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '12 Apr 2021'	Xavier Morales (b) (4)	21 Apr 2021 20:23:21
	(b) (4)	

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	Xavier Morales (b) (4)	21 Apr 2021 20:23:21
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:14:24**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 20:23:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 18:23:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Apr 2021 18:23:20
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	22 Apr 2021 18:23:20
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 20:23:21
User entered empty.	Xavier Morales (b) (4)	21 Apr 2021 20:23:21



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '17 Apr 2021'	Xavier Morales (b) (4)	21 Apr 2021 20:23:21
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:14:24**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	Xavier Morales (b) (4)	21 Apr 2021 20:23:21
	(b) (4)	

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:14:24**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 20:23:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 18:23:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Apr 2021 18:23:20
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	22 Apr 2021 18:23:20
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 20:23:21
User entered empty.	Xavier Morales (b) (4)	21 Apr 2021 20:23:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User closed query 'PV Query Urgent: Please provide missing seriousness criteria as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 19:32:30
Query 'PV Query Urgent: Please provide missing seriousness criteria as soon as possible.' answered with 'added' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	22 Apr 2021 19:28:30
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	22 Apr 2021 19:28:21
User opened query 'PV Query Urgent: Please provide missing seriousness criteria as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 19:18:39
User closed query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 19:09:56
Query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' answered with 'information has been updated' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	22 Apr 2021 18:24:24
User opened query 'PV Query Urgent: Please confirm if the event was considered SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 17:15:07
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	21 Apr 2021 20:23:21
User entered 'Yes (Y)'	Xavier Morales (b) (4) (b) (4)	21 Apr 2021 20:23:21

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	Xavier Morales (b) (4)	21 Apr 2021 20:23:21
	(b) (4)	

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	Xavier Morales (b) (4)	21 Apr 2021 20:23:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 07:30:30
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'added' (Site from System).	Joanna Gurrola Mahoney (b) (4)	22 Apr 2021 19:29:13
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	22 Apr 2021 19:28:21
User entered '1' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	22 Apr 2021 19:28:21
User entered '0'	Xavier Morales (b) (4)	21 Apr 2021 20:23:21



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '12 Apr 2020' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	22 Apr 2021 19:29:05
User entered empty.	Xavier Morales (b) (4)	21 Apr 2021 20:23:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '17 Apr 2021' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	22 Apr 2021 19:29:05
User entered empty.	Xavier Morales (b) (4)	21 Apr 2021 20:23:21
	(b) (4)	

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	Xavier Morales (b) (4)	21 Apr 2021 20:23:21
	(b) (4)	

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	Xavier Morales (b) (4)	21 Apr 2021 20:23:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	Xavier Morales (b) (4)	21 Apr 2021 20:23:21
	(b) (4)	

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	Xavier Morales (b) (4)	21 Apr 2021 20:23:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	Xavier Morales (b) (4)	21 Apr 2021 20:23:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 19:09:54
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	22 Apr 2021 18:23:29
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 18:23:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Apr 2021 18:23:20
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	22 Apr 2021 18:23:20
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 17:15:36
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 20:23:21
User entered empty.	Xavier Morales (b) (4) (b) (4)	21 Apr 2021 20:23:21



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 19:09:52
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated' (Site from Safety).	Joanna Gurrola Mahoney (b) (4)	22 Apr 2021 18:23:37
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 18:23:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Apr 2021 18:23:20
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	22 Apr 2021 18:23:20
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 17:15:44
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 20:23:21
User entered empty.	Xavier Morales (b) (4) (b) (4)	21 Apr 2021 20:23:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

Action taken with investigational product

Audit	User	Time (GMT)
Query 'PV Query: As the last dose of the vaccine, mRNA-1273-P301, was given on 04 Nov 2020, please update the action taken with vaccine from none to not applicable. ' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 22:21:33
Signature has been broken.	(b) (4), (b) (6)	03 May 2021 22:20:51
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error		03 May 2021 22:20:51
User opened query 'PV Query: As the last dose of the vaccine, mRNA-1273-P301, was given on 04 Nov 2020, please update the action taken with vaccine from none to not applicable. ' (Site from Safety).		29 Apr 2021 16:18:11
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 18:23:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Apr 2021 18:23:20
User entered 'None (NONE)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	22 Apr 2021 18:23:20
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 20:23:21
User entered empty.	Xavier Morales (b) (4)	21 Apr 2021 20:23:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

None

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Apr 2021 18:24:00
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	21 Apr 2021 20:23:21
User entered '0'	Xavier Morales (b) (4) (b) (4)	21 Apr 2021 20:23:21

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '1' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	22 Apr 2021 18:24:00
User entered '0'	Xavier Morales (b) (4)	21 Apr 2021 20:23:21

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	Xavier Morales (b) (4)	21 Apr 2021 20:23:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 18:23:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Apr 2021 18:23:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Joanna Gurrola Mahoney (b) (4)	22 Apr 2021 18:23:20
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 20:23:21
User entered empty.	Xavier Morales (b) (4) (b) (4)	21 Apr 2021 20:23:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	Xavier Morales (b) (4)	21 Apr 2021 20:23:21
	(b) (4)	

US3252624

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:14:24

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.	(b) (4), (b) (6)	29 Apr 2021 16:19:21
' (Site from Safety).		
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 16:19:15
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 16:19:06
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)	29 Apr 2021 16:18:21
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	Xavier Morales (b) (4)	21 Apr 2021 20:23:21
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 20:23:21

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Apr 2021 18:23:20

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:14:24**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Aching joints - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 05:32:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 05:32:52
Data point term sent to Coder	System	23 Apr 2021 05:32:10
User entered 'joint aches in several joints'	(b) (4), (b) (6)	23 Apr 2021 05:31:35

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 05:31:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 05:31:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 05:31:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '10 Oct 2020'	(b) (4), (b) (6)	23 Apr 2021 05:31:35



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User closed query 'Start time is present for an AE thatSystem did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).		23 Apr 2021 05:31:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 05:31:41
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	23 Apr 2021 05:31:35
User entered '22:13'	(b) (4), (b) (6)	23 Apr 2021 05:31:35

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:14:24**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User entered empty.	System	23 Apr 2021 05:31:41
User entered '10 Oct 2020 22:13'	System	23 Apr 2021 05:31:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 05:31:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:24

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '12 Oct 2020'	(b) (4), (b) (6)	23 Apr 2021 05:31:35

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:14:24**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:31:35

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:14:24**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User entered empty.	System	23 Apr 2021 05:31:35

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	23 Apr 2021 05:31:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 05:31:35



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:24

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:31:35

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:31:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:31:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:31:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:24

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:31:35

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:31:35

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:31:35

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:31:35



**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:31:35

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:31:35

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'Related (RELATED)'	(b) (4), (b) (6)	23 Apr 2021 05:31:35

US3252624

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:14:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Apr 2021 05:31:35

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'None (NONE)'	(b) (4), (b) (6)	23 Apr 2021 05:31:35

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:14:24**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'I'	(b) (4), (b) (6)	23 Apr 2021 05:31:35

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:31:35

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:31:35



**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	23 Apr 2021 05:31:35

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:14:24**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:31:35

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:31:35

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User entered '0'	System	23 Apr 2021 05:31:35

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57
User entered '0'	System	23 Apr 2021 05:31:35

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:57

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:14:24**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 05:38:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 05:38:52
Data point term sent to Coder	System	23 Apr 2021 05:38:11
User entered 'muscle aches all over body'	(b) (4), (b) (6)	23 Apr 2021 05:37:22



US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '10 Oct 2020'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User closed query 'Start time is present for an AE thatSystem did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).		23 Apr 2021 05:37:34
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 05:37:34
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	23 Apr 2021 05:37:22
User entered '22:13'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User entered empty.	System	23 Apr 2021 05:37:34
User entered '10 Oct 2020 22:13'	System	23 Apr 2021 05:37:22

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	23 Apr 2021 05:37:34
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 05:37:34
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	23 Apr 2021 05:37:22
User entered '12 Oct 2021'	(b) (4), (b) (6)	23 Apr 2021 05:37:22



**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:14:24**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:37:22

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User entered empty.	System	23 Apr 2021 05:37:22

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:37:22



US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:37:22

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:37:22

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:37:22

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'Related (RELATED)'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Apr 2021 05:37:22



**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'None (NONE)'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:14:24**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'I'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

US3252624

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:14:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	23 Apr 2021 05:37:22

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:14:24**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:37:22

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:37:22

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User entered '0'	System	23 Apr 2021 05:37:22



**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59
User entered '0'	System	23 Apr 2021 05:37:22

**US3252624**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:33:59

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:14:24

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:54:45
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:17:03
User closed query 'Per DM CLR: Per Diary Dose 2 Day 1 and 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:25:05
Query 'Per DM CLR: Per Diary Dose 2 Day 1 and 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'Ibuprofen for the indication of arm pain has been recorded in the prior/CM form ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 07:08:00
User opened query 'Per DM CLR: Per Diary Dose 2 Day 1 and 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:34:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:39:17

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;VALSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 06:33:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 06:33:01
Data point term sent to Coder	System	19 Nov 2020 06:31:26
Coding entries removed.	Shannon Moyer (b) (4) (b) (4)	19 Nov 2020 06:30:37
User entered 'VALSARTAN / HYDROCHLOROTHIAZIDE' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	19 Nov 2020 06:30:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;VALSARTAN, PRODUCTSYNONYM: VALSARTAN/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:45:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 16:45:23
Data point term sent to Coder	System	06 Oct 2020 16:44:38
User entered 'Valsartan/Hydrochlorothiazide'	(b) (4), (b) (6)	06 Oct 2020 16:44:23

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:44:23

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Hypertension'	(b) (4), (b) (6)	06 Oct 2020 16:44:23

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '160/25'	(b) (4), (b) (6)	06 Oct 2020 16:44:23

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Oct 2020 16:44:23



US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:14:24**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:44:23

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Oct 2020 16:44:23

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:14:24**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:44:23

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Oct 2020 16:44:23

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:14:24**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:44:23

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'UN UNK 2016'	(b) (4), (b) (6)	06 Oct 2020 16:44:23

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 16:44:23

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 16:44:23



US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:14:24**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:44:23

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:14:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 16:44:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Oct 2020 16:44:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 16:44:32
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 16:44:23
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 16:44:23

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:44:23

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 16:44:23

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:14:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 16:44:23

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:47
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:43:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 15:43:21
Data point term sent to Coder	System	12 Oct 2020 15:42:19
User entered 'ibuprofen'	Joanna Gurrola Mahoney (b) (4)	12 Oct 2020 15:42:01

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:47
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	12 Oct 2020 15:42:01

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:47
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the ARM PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ARM PAIN did not meet the AE reporting criteria.'	(b) (4), (b) (6)	11 Feb 2021 09:44:10
(Site from DM).		
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the ARM PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ARM PAIN did not meet the AE reporting criteria.'	Uche Ehiemua (b) (4)	10 Feb 2021 14:53:24
answered with 'Solicited adverse reaction of ARM PAIN does not meet the AE reporting criteria.' (Site from DM).	(b) (4)	





US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:47
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '800'	Joanna Gurrola Mahoney (b) (4)	12 Oct 2020 15:42:01

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:47
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'mg (mg)'	Joanna Gurrola Mahoney (b) (4)	12 Oct 2020 15:42:01

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:47
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered empty.	Joanna Gurrola Mahoney (b) (4)	12 Oct 2020 15:42:01

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:47
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'as needed (PRN)'	Joanna Gurrola Mahoney (b) (4)	12 Oct 2020 15:42:01

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:47
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered empty.	Joanna Gurrola Mahoney (b) (4)	12 Oct 2020 15:42:01

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:47
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Oral (ORAL)'	Joanna Gurrola Mahoney (b) (4)	12 Oct 2020 15:42:01

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:14:24**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:47
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered empty.	Joanna Gurrola Mahoney (b) (4)	12 Oct 2020 15:42:01



US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:24

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:47
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '6 Oct 2020'	Joanna Gurrola Mahoney (b) (4)	12 Oct 2020 15:42:01

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:47
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '0'	Joanna Gurrola Mahoney (b) (4)	12 Oct 2020 15:42:01

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:47
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'No (N)'	Joanna Gurrola Mahoney (b) (4)	12 Oct 2020 15:42:01

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:14:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:47
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '6 Oct 2020'	Joanna Gurrola Mahoney (b) (4)	12 Oct 2020 15:42:01

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:47
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Yes (Y)'	Joanna Gurrola Mahoney (b) (4)	12 Oct 2020 15:42:01

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:47
User entered empty.	System	12 Oct 2020 15:42:01

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:47
User entered empty.	System	12 Oct 2020 15:42:01

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:14:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:47
User entered empty.	System	12 Oct 2020 15:42:01



US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 14:56:47
User coded data point as Term Coded data point by	Coder Import (b) (4)	10 Feb 2021 14:56:47
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	10 Feb 2021 14:56:00
User entered 'IBUPROFEN'	Uche Ehiemua (b) (4)	10 Feb 2021 14:55:46
	(b) (4)	

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'No (N)'	Uche Ehiemua (b) (4)	10 Feb 2021 14:55:46
	(b) (4)	

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'ARM PAIN'	Uche Ehiemua (b) (4)	10 Feb 2021 14:55:46
	(b) (4)	

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '400'	Uche Ehiemua (b) (4)	10 Feb 2021 14:55:46
	(b) (4)	

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'mg (mg)'	Uche Ehiemua (b) (4)	10 Feb 2021 14:55:46
	(b) (4)	

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:14:24**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered empty.	Uche Ehiemua (b) (4)	10 Feb 2021 14:55:46
	(b) (4)	

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'once (ONCE)'	Uche Ehiemua (b) (4)	10 Feb 2021 14:55:46
	(b) (4)	

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered empty.	Uche Ehiemua (b) (4)	10 Feb 2021 14:55:46
	(b) (4)	



**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Oral (ORAL)'	Uche Ehiemua (b) (4)	10 Feb 2021 14:55:46
	(b) (4)	

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered empty.	Uche Ehiemua (b) (4)	10 Feb 2021 14:55:46
	(b) (4)	

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '4 Nov 2020'	Uche Ehiemua (b) (4)	10 Feb 2021 14:55:46
	(b) (4)	

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '0'	Uche Ehiemua (b) (4)	10 Feb 2021 14:55:46
	(b) (4)	

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'No (N)'	Uche Ehiemua (b) (4)	10 Feb 2021 14:55:46
	(b) (4)	

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:14:24**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '4 Nov 2020'	Uche Ehiemua (b) (4)	10 Feb 2021 14:55:46
	(b) (4)	

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:49
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Yes (Y)'	Uche Ehiemua (b) (4)	10 Feb 2021 14:55:46
	(b) (4)	

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:14:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:49
User entered empty.	System	10 Feb 2021 14:55:46



US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:49
User entered empty.	System	10 Feb 2021 14:55:46

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:05:49
User entered empty.	System	10 Feb 2021 14:55:46

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 07:03:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 07:03:46
Data point term sent to Coder	System	18 Feb 2021 07:03:14
User entered 'Trulicity'	(b) (4), (b) (6)	18 Feb 2021 07:02:58

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'No (N)'	(b) (4), (b) (6)	18 Feb 2021 07:02:58

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:14:24**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'diabetes type 2'	(b) (4), (b) (6)	18 Feb 2021 07:02:58

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:14:24**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '1.5'	(b) (4), (b) (6)	18 Feb 2021 07:02:58

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'mg (mg)'	(b) (4), (b) (6)	18 Feb 2021 07:02:58

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:14:24**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 07:02:58



US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'every week (QS)'	(b) (4), (b) (6)	18 Feb 2021 07:02:58

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:14:24**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 07:02:58

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:14:24**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	18 Feb 2021 07:02:58

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:14:24**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 07:02:58

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:14:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '23 Dec 2020'	(b) (4), (b) (6)	18 Feb 2021 07:02:58

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '0'	(b) (4), (b) (6)	18 Feb 2021 07:02:58

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:14:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Feb 2021 07:02:58

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:14:24**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 07:02:58



US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:14:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'No (N)'	(b) (4), (b) (6)	18 Feb 2021 07:02:58

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:14:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Feb 2021 07:02:58

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:14:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Feb 2021 07:02:58

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:14:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	18 Feb 2021 07:02:58

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 07:04:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 07:04:56
Data point term sent to Coder	System	18 Feb 2021 07:04:15
User entered 'Metformin'	(b) (4), (b) (6)	18 Feb 2021 07:04:12

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'No (N)'	(b) (4), (b) (6)	18 Feb 2021 07:04:12

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 11:20:22
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Updated!' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 02:26:16
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 15:59:33
User entered 'diabetes type 2'	(b) (4), (b) (6)	18 Feb 2021 07:04:12

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:14:24**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '500'	(b) (4), (b) (6)	18 Feb 2021 07:04:12



US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'mg (mg)'	(b) (4), (b) (6)	18 Feb 2021 07:04:12

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:14:24**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 07:04:12

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'once daily (QD)'	(b) (4), (b) (6)	18 Feb 2021 07:04:12

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 07:04:12

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	18 Feb 2021 07:04:12

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:14:24**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 07:04:12

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '23 Dec 2020'	(b) (4), (b) (6)	18 Feb 2021 07:04:12

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered '0'	(b) (4), (b) (6)	18 Feb 2021 07:04:12



**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:14:24**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Feb 2021 07:04:12

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 07:04:12

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:14:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Apr 2021 21:04:35
User entered 'No (N)'	(b) (4), (b) (6)	18 Feb 2021 07:04:12

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:14:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Feb 2021 07:04:12

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:14:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Feb 2021 07:04:12

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:14:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Feb 2021 07:04:12

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 08:25:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 08:25:44
Data point term sent to Coder	System	23 Apr 2021 05:22:06
User entered 'doxycycline'	(b) (4), (b) (6)	23 Apr 2021 05:21:48

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 05:21:48



US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'Bacterial Pneumonia'	(b) (4), (b) (6)	23 Apr 2021 05:21:48

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:14:24**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '500'	(b) (4), (b) (6)	23 Apr 2021 05:21:48

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Apr 2021 05:21:48

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:14:24**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:21:48

US3252624

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:14:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'three times daily (TID)'	(b) (4), (b) (6)	23 Apr 2021 05:21:48

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:14:24**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:21:48

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:14:24**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Apr 2021 05:21:48

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:14:24**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:21:48



US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:14:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '17 Apr 2021'	(b) (4), (b) (6)	23 Apr 2021 05:21:48

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:14:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 05:21:48

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:14:24**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 05:21:48

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:14:24**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 05:21:48

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:14:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 05:21:48

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:14:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	23 Apr 2021 05:21:48

US3252624

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:14:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 05:21:48

**US3252624**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:14:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 05:21:48



US3252624

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 16:14:24**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	05 Mar 2021 22:17:03
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 16:44:45

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'USA-US108-2021-MRNA-1273-P301000021'	System	22 Apr 2021 14:57:15

US3252624

Folder: SAE USA-US108-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 19:33:53
Un-reviewed for Safety.	System	22 Apr 2021 19:28:21
Signature has been broken.	System	22 Apr 2021 19:28:21
User entered 'Yes (Y)'	System	22 Apr 2021 19:28:21
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'No (N)'	System	22 Apr 2021 14:57:15

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'No (N)'	System	22 Apr 2021 14:57:15

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'No (N)'	System	22 Apr 2021 14:57:15

US3252624

Folder: SAE USA-US108-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 19:33:53
Un-reviewed for Safety.	System	22 Apr 2021 19:28:21
Signature has been broken.	System	22 Apr 2021 19:28:21
User entered 'Yes (Y)'	System	22 Apr 2021 19:28:21
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'No (N)'	System	22 Apr 2021 14:57:15

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'No (N)'	System	22 Apr 2021 14:57:15

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'No (N)'	System	22 Apr 2021 14:57:15



**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'No (N)'	System	22 Apr 2021 14:57:15

US3252624

Folder: SAE USA-US108-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'Joel'	System	22 Apr 2021 14:57:15

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'Solis'	System	22 Apr 2021 14:57:15

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered '5201 N. 10th Street'	System	22 Apr 2021 14:57:15

US3252624

Folder: SAE USA-US108-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:24

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 19:33:49
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'Mcallen'	System	22 Apr 2021 14:57:15

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'TX'	System	22 Apr 2021 14:57:15

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'carmpa'	System	22 Apr 2021 14:57:15

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 19:10:57
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 19:10:07
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
User entered 'US'	System	22 Apr 2021 14:57:45



**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 19:34:04
User entered '2'	System	22 Apr 2021 19:10:20
User entered '1'	System	22 Apr 2021 14:57:45

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'USA-US108-2021-MRNA-1273-P301000021'	System	22 Apr 2021 14:57:15

US3252624

Folder: SAE USA-US108-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 19:33:53
Un-reviewed for Safety.	System	22 Apr 2021 19:28:21
Signature has been broken.	System	22 Apr 2021 19:28:21
User entered 'Yes (Y)'	System	22 Apr 2021 19:28:21
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'No (N)'	System	22 Apr 2021 14:57:15

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'No (N)'	System	22 Apr 2021 14:57:15

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'No (N)'	System	22 Apr 2021 14:57:15

US3252624

Folder: SAE USA-US108-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 19:33:53
Un-reviewed for Safety.	System	22 Apr 2021 19:28:21
Signature has been broken.	System	22 Apr 2021 19:28:21
User entered 'Yes (Y)'	System	22 Apr 2021 19:28:21
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'No (N)'	System	22 Apr 2021 14:57:15

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'No (N)'	System	22 Apr 2021 14:57:15

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'No (N)'	System	22 Apr 2021 14:57:15



**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'No (N)'	System	22 Apr 2021 14:57:15

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'Joel'	System	22 Apr 2021 14:57:15

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'Solis'	System	22 Apr 2021 14:57:15

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered '5201 N. 10th Street'	System	22 Apr 2021 14:57:15

US3252624

Folder: SAE USA-US108-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:14:24

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 19:33:49
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'Mcallen'	System	22 Apr 2021 14:57:15

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'TX'	System	22 Apr 2021 14:57:15

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 14:57:37
User entered 'carmpa'	System	22 Apr 2021 14:57:15

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 19:10:57
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 19:10:07
User signature succeeded.	Joel Solis (b) (4)	22 Apr 2021 19:08:19
User entered 'US'	System	22 Apr 2021 14:57:45



**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:14:24**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 19:34:04
User entered '2'	System	22 Apr 2021 19:10:20
User entered '1'	System	22 Apr 2021 14:57:45

**US3252624**

**Folder: SAE USA-US108-2021-MRNA-1273-P301000021**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:14:24**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered '22/Apr/2021 14:34'	System	22 Apr 2021 19:34:04

US3252624

Folder: SAE USA-US108-2021-MRNA-1273-P301000021

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:14:24

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Joel Solis (b) (4)	28 Apr 2021 11:51:32
User entered 'I'	(b) (4), (b) (6)	22 Apr 2021 19:34:04