

US3642076 (Prod: University of California San Diego)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:13:13

All time stamps listed in this document are displayed in GMT

US3642076

Form: Participant Creation

Data signed: (b) (4) 13 Feb 2021 02:38:30

Generated On: 10 Jun 2021 09:13:13

---

Participant ID

US3642076

---

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

---

---

US3642076

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3642076

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	65
Age Units	YEARS
Age (Derived)	65
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3642076

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Date of Informed Consent ( <i>dd MMM yyyy</i> )	1 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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

US3642076

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

---

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

---

US3642076

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

---

Were any significant conditions reported?

Yes ☒

No ☐

---

US3642076

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Mar 2021 23:55:30

Generated On: 10 Jun 2021 09:13:13

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



US3642076

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Mar 2021 23:55:30

Generated On: 10 Jun 2021 09:13:13

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

US3642076

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Mar 2021 23:55:30

Generated On: 10 Jun 2021 09:13:13

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3642076

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Mar 2021 23:55:30

Generated On: 10 Jun 2021 09:13:13

Condition	PROSTATE ISSUE
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3642076

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Mar 2021 23:55:30

Generated On: 10 Jun 2021 09:13:13

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3642076

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Mar 2021 23:55:30

Generated On: 10 Jun 2021 09:13:13

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

US3642076

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Mar 2021 23:55:30

Generated On: 10 Jun 2021 09:13:13

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

US3642076

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Mar 2021 23:55:30

Generated On: 10 Jun 2021 09:13:13

Condition	RENAL CELL CARCINOMA
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

US3642076

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Mar 2021 23:55:30

Generated On: 10 Jun 2021 09:13:13

Condition	HEADACHES
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3642076

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Mar 2021 23:55:30

Generated On: 10 Jun 2021 09:13:13

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

US3642076

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	01 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	15:30 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 15:30
Height ( <i>xxx.x</i> )	189.5 cm
Weight ( <i>xxx.x</i> )	123.5 kg
BMI ( <i>xxx.x</i> )	34.39129 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)	

US3642076

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 2020

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

US3642076

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

---

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

---

**Specify**

---

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

**No Risk Identified** False

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

US3642076

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

<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>	

US3642076

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3642076

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

What was the date of randomization? (dd MMM yyyy) 01 SEP 2020

What was the participant's randomization number? 189490

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 ☒

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Height	ND - Not Done
Weight	ND - Not Done



US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

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)	1 SEP 2020
Time of assessment (00:00-23:59)	15:30 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 15:30
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)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

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)	1 SEP 2020
Time of assessment (00:00-23:59)	18:15 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 18:15
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3642076

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

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.*

US3642076

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

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) 1 SEP 2020

What was the treatment time? (00:00-23:59) 17:34 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 17:34

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

US3642076

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 SEP 2020

Collection time (00:00-23:59)

16:45 (24 HR)

Collection date and time (derived)

01 SEP 2020 16:45

US3642076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Collection date (dd MMM yyyy)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:50	01 SEP 2020 16:50
Nasopharyngeal Swab 2	No		

US3642076

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

**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

98.7 °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

01 SEP 2020 18:07

PC Open Date & Time

01 SEP 2020 17:54

PC Close Date & Time

01 SEP 2020 20:24



US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	02 SEP 2020 10:44
PC Open Date & Time	01 SEP 2020 21:19
PC Close Date & Time	02 SEP 2020 11:59

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**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

98.1 °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

02 SEP 2020 22:41

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:13

---

**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

98.8 °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

03 SEP 2020 12:37

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:13

**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

97.9 °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

04 SEP 2020 23:19

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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 SEP 2020 13:04

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:13

**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

97.7 °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

06 SEP 2020 12:06

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 12:13

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

**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

01 SEP 2020 18:08

PC Open Date & Time

01 SEP 2020 17:54

PC Close Date & Time

01 SEP 2020 20:24



US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 10:45

PC Open Date & Time

01 SEP 2020 21:19

PC Close Date & Time

02 SEP 2020 11:59

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 22:42

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 12:38

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 23:19

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:13

**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

05 SEP 2020 13:04

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:13

**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

06 SEP 2020 12:06

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:13

**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

07 SEP 2020 12:14

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

**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 ☐



US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 18:09
PC Open Date & Time	01 SEP 2020 17:54
PC Close Date & Time	01 SEP 2020 20:24

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

**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 ☐

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 10:45
PC Open Date & Time	01 SEP 2020 21:19
PC Close Date & Time	02 SEP 2020 11:59

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:13

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 ☒

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:13

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 22:42
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:13

**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  
EAB) (1725)

53 of 2395

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:13

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 12:39
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:13

**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 ☒



US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:13

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 23:20
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

57 of 2395

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:13

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 13:05
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:13

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

59 of 2395

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:13

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

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:13

**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 ☒

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:13

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 12:14
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3642076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3642076

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:38:53

Generated On: 10 Jun 2021 09:13:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642076

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:38:53

Generated On: 10 Jun 2021 09:13:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642076

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

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

Visit date (dd MMM yyyy)	30 SEP 2020
--------------------------	-------------

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

Folder OID	VISIT2
------------	--------

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

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)	30 SEP 2020
Time of assessment (00:00-23:59)	13:26 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 13:26
Temperature (xxx.x)	97 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	15:06 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 15:06
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG



US3642076

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3642076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

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) 30 SEP 2020

What was the treatment time? (00:00-23:59) 14:35 (24 HR)

Treatment Date and Time (derived) 30 SEP 2020 14:35

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

US3642076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 SEP 2020

Collection time (00:00-23:59)

13:50 (24 HR)

Collection date and time (derived)

30 SEP 2020 13:50

US3642076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:52	30 SEP 2020 13:52
Nasopharyngeal Swab 2	No		

US3642076

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 14:58

PC Open Date & Time

30 SEP 2020 14:55

PC Close Date & Time

30 SEP 2020 17:25

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °F

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

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

PC Time Stamp	30 SEP 2020 20:34
PC Open Date & Time	30 SEP 2020 18:20
PC Close Date & Time	01 OCT 2020 11:59

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 16:05

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59



US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 12:08

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:13

**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

03 OCT 2020 13:27

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

04 OCT 2020 21:55

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:13

**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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 12:04

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 12:26

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

**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

30 SEP 2020 14:59

PC Open Date & Time

30 SEP 2020 14:55

PC Close Date & Time

30 SEP 2020 17:25

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 20:35

PC Open Date & Time

30 SEP 2020 18:20

PC Close Date & Time

01 OCT 2020 11:59

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 16:06

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59



US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 12:07

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 13:27

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:13

**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

04 OCT 2020 21:56

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:13

**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

05 OCT 2020 12:05

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:13

**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

06 OCT 2020 12:27

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

**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 ☐

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 14:59
PC Open Date & Time	30 SEP 2020 14:55
PC Close Date & Time	30 SEP 2020 17:25

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

**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 ☐



US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 20:36
---------------	-------------------

PC Open Date & Time	30 SEP 2020 18:20
---------------------	-------------------

PC Close Date & Time	01 OCT 2020 11:59
----------------------	-------------------

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

97 of 2395

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:13

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 16:07
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:13

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

99 of 2395

EAB) (1725)

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:13

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:08
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:13

**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)

101 of 2395

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:13

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 13:28
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:13

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

103 of 2395

EAB) (1725)



US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:13

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 21:57
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:13

**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 ☒

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:13

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

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:13

**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 ☒

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:13

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 12:27
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3642076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642076

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3642076

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642076

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3642076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	28 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	13:38 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 13:38
Temperature ( <i>xxx.x</i> )	97 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	104 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3642076

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 OCT 2020

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

US3642076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 OCT 2020

Collection time (00:00-23:59)

14:05 (24 HR)

Collection date and time (derived)

28 OCT 2020 14:05

US3642076

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3642076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	01 NOV 2020 10:17:19
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3642076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 00:08:30

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3642076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 00:50:24

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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 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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

19 NOV 2020 00:01

---

[Patient Cloud Close Date & Time](#)

---

23 NOV 2020 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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	29 NOV 2020 09:19:52
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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	06 DEC 2020 06:23:49
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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

12 DEC 2020 13:01:37

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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

17 DEC 2020 00:01:52

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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

24 DEC 2020 00:01:46

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 DEC 2020 09:50:40
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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

07 JAN 2021 11:25:29

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

<b>TIMEPOINT</b>	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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 12:40:14
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 07:34:10

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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

28 JAN 2021 08:51:12

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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 <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	04 FEB 2021 05:24:24
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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 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	11 FEB 2021 09:01:07
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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

18 FEB 2021 12:27:43

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	25 FEB 2021 08:46:55
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	04 MAR 2021 00:02:18
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 MAR 2021 03:47:35
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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

18 MAR 2021 02:48:48

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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

25 MAR 2021 06:40:58

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 00:02:13

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 12:01:52

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 00:03:39

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 06:56:07

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 00:01:40

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

13 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

17 MAY 2021 23:59

---



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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="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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

27 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

31 MAY 2021 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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="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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 299

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

01 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

05 JUL 2021 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 313

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

08 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

12 JUL 2021 23:59

---



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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="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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

12 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

16 AUG 2021 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

19 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

23 AUG 2021 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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°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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

02 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

06 SEP 2021 23:59

---



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

28 OCT 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

01 NOV 2021 23:59

---



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

04 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

08 NOV 2021 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

18 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

22 NOV 2021 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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°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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

25 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

29 NOV 2021 23:59

---



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

---

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 DEC 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 DEC 2021 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

13 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

17 JAN 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

---



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

24 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

28 FEB 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

03 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

07 MAR 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

24 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

28 MAR 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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 <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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

14 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

18 APR 2022 23:59

---



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

21 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

25 APR 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

28 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

02 MAY 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

12 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

16 MAY 2022 23:59

---



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

19 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

23 MAY 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

26 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

30 MAY 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

16 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

20 JUN 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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 <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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

07 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 JUL 2022 23:59

---



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

28 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

01 AUG 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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 <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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

04 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

08 AUG 2022 23:59

---



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

11 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

15 AUG 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

18 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

22 AUG 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

25 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

29 AUG 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

---



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

---

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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="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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2022 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2022 23:59

US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

**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 ☐

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59



US3642076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

03 NOV 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

07 NOV 2022 23:59

---

US3642076

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:13:13

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		04 MAR 2021 00:02:40

US3642076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

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*

US3642076

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642076

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:38:32

Generated On: 10 Jun 2021 09:13:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642076

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:38:32

Generated On: 10 Jun 2021 09:13:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:38:53

Generated On: 10 Jun 2021 09:13:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3642076

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:38:32

Generated On: 10 Jun 2021 09:13:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 02:12:56

Generated On: 10 Jun 2021 09:13:13

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 MAR 2021

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

Comments  
ATTEMPT 1 03MAR2021  
VOICEMAIL NOT SET UP

*If Contact Not Made, please provide Comments*

ATTEMPT 2 03MAR2021 1755P

ATTEMPT 3 08MAR2021 0940A  
EMAIL SENT

US3642076

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 02:12:56

Generated On: 10 Jun 2021 09:13:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642076

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3642076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3642076

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 MAR 2021

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

US3642076

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 MAR 2021
Collection time (00:00-23:59)	15:17 (24 HR)
Collection date and time (derived)	05 MAR 2021 15:17

US3642076

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3642076

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 21:24:09

Generated On: 10 Jun 2021 09:13:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642076

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 21:24:09

Generated On: 10 Jun 2021 09:13:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3642076**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3642076**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3642076

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:13:13

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"/>

**US3642076**

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

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

**Generated On: 10 Jun 2021 09:13:13**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3642076

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

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:38:32

Generated On: 10 Jun 2021 09:13:13

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

Visit date (dd MMM yyyy)	21 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
------------	---------------

US3642076

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

Form: Unblinding

Data signed: (b) (4) 13 Mar 2021 02:12:56

Generated On: 10 Jun 2021 09:13:13

Date of updated informed consent ( <i>dd MMM yyyy</i> )	21 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	08 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1



US3642076

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:38:32

Generated On: 10 Jun 2021 09:13:13

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3642076

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:38:32

Generated On: 10 Jun 2021 09:13:13

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 JAN 2021
Time of assessment (00:00-23:59)	09:09 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 09:09
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)	119 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3642076

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:38:32

Generated On: 10 Jun 2021 09:13:13

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	21 JAN 2021
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 10:30
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)	114 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3642076

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

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:38:32

Generated On: 10 Jun 2021 09:13:13

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.*

US3642076

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

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:38:32

Generated On: 10 Jun 2021 09:13:13

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 21 JAN 2021

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

Treatment Date and Time (derived) 21 JAN 2021 09:59

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

US3642076

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:38:32

Generated On: 10 Jun 2021 09:13:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 JAN 2021

Collection time (00:00-23:59)

09:45 (24 HR)

Collection date and time (derived)

21 JAN 2021 09:45

US3642076

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Feb 2021 02:38:31

Generated On: 10 Jun 2021 09:13:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 JAN 2021

Collection time (00:00 - 23:59)

09:47

Collection Date and Time (derived)

21 JAN 2021 09:47

US3642076

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

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:38:32

Generated On: 10 Jun 2021 09:13:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3642076

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642076

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:38:54

Generated On: 10 Jun 2021 09:13:13

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

US3642076

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Mar 2021 02:12:56

Generated On: 10 Jun 2021 09:13:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 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	OLD29

US3642076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Mar 2021 02:12:56

Generated On: 10 Jun 2021 09:13:13

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 MAR 2021
Time of assessment (00:00-23:59)	14:16 (24 HR)
Vital Signs Date and Time (derived)	05 MAR 2021 14:16
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3642076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Mar 2021 02:12:56

Generated On: 10 Jun 2021 09:13:13

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 MAR 2021
Time of assessment (00:00-23:59)	16:06 (24 HR)
Vital Signs Date and Time (derived)	05 MAR 2021 16:06
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)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	102 mmHg
Diastolic Blood Pressure units	MMHG

US3642076

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Mar 2021 02:12:56

Generated On: 10 Jun 2021 09:13:13

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

05 MAR 2021

---

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

---

US3642076

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 13 Mar 2021 02:12:56

Generated On: 10 Jun 2021 09:13:13

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 05 MAR 2021

What was the treatment time? (00:00-23:59) 15:33 (24 HR)

Treatment Date and Time (derived) 05 MAR 2021 15:33

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

US3642076

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 02:12:56

Generated On: 10 Jun 2021 09:13:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3642076

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 02:12:56

Generated On: 10 Jun 2021 09:13:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3642076

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 02:12:56

Generated On: 10 Jun 2021 09:13:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642076

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3642076

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3642076

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

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.*

US3642076

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 APR 2021
Collection time (00:00-23:59)	15:37 (24 HR)
Collection date and time (derived)	05 APR 2021 15:37

US3642076

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 06 Mar 2021 01:40:32

Generated On: 10 Jun 2021 09:13:13

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3642076

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Apr 2021 18:01:59

Generated On: 10 Jun 2021 09:13:13

AEID	USA-US109-2021-MRNA-1273-P30 1000007
Adverse event	POSSIBLE RELAPSE OF RENAL CELL CARCINOMA METASTASIZED TO HIS LUNGS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	24 FEB 2021
Admitted to ICU?	Yes <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

351 of 2395



US3642076

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Apr 2021 18:01:59

Generated On: 10 Jun 2021 09:13:13

	No	<input checked="" type="radio"/>
	Unknown	<input type="radio"/>
<hr/>		
Number of Days in ICU		
Persistent or significant disability or incapacity	False	<input type="radio"/>
Congenital anomaly or birth defect	False	<input type="radio"/>
Other medically important event	False	<input type="radio"/>
Relationship to investigational product	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
Action taken with investigational product	None	<input checked="" type="radio"/>
	Dose Delayed	<input type="radio"/>
	Investigational Product	<input type="radio"/>
	Withdrawn	<input type="radio"/>
	Not Applicable	<input type="radio"/>
<hr/>		
Other action taken (check all that apply)		
None	False	<input type="radio"/>
Concomitant Medication	True	<input type="radio"/>
Concomitant Procedure	True	<input type="radio"/>
Outcome	Fatal	<input type="radio"/>
	Not Recovered/Not Resolved	<input type="radio"/>
	Recovered/Resolved	<input type="radio"/>
	Recovered/Resolved with Sequelae	<input type="radio"/>
	Recovering/Resolving	<input checked="" type="radio"/>
	Unknown	<input type="radio"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
<hr/>		
Narrative		

US3642076

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Apr 2021 18:01:59

Generated On: 10 Jun 2021 09:13:13

---

SUBJECT WAS HOSPITALIZED  
FOR 2 DAYS FOR  
OBSERVATION DUE TO  
SYMPTOMS INDICATING  
RELAPSE OF RENAL CELL  
CARCINOMA METASTASIZED  
TO  
HIS LUNGS. HE WAS  
DIAGNOSED WITH RENAL CELL  
CARCINOMA 2015 AND WAS  
OFF TREATMENT SINCE 2019.  
SUBJECT WILL CONTINUE TO  
REMAIN IN THE STUDY AND  
WANTS TO CONTINUE GETTING  
SECOND IMMUNIZATION.

---

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

---

US3642076

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Apr 2021 18:01:59

Generated On: 10 Jun 2021 09:13:13

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

354 of 2395

US3642076

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Apr 2021 18:01:59

Generated On: 10 Jun 2021 09:13:13

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

US3642076

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Apr 2021 18:01:59

Generated On: 10 Jun 2021 09:13:13

---

PATIENT DISCHARGED FROM  
HOSPITAL AFTER OVERNIGHT  
STAY FOR UNCONTROLLED  
COUGH (SEE PREVIOUS  
RESOLVED AE LOG LINE3).  
COUGH NOW CONTROLLED  
AND HE WAS DISCHARGD  
HOME ON PO GUAIFENESIN  
(EXTENDED RELEASE) AND  
BENZONATATE.

UPDATE: HE REPORTS THAT  
HE HAS STOPPED TAKING  
BENZONATATE AND  
GUAIFENESIN AS OF 01APR2021.  
HE HAS NOT FOLLOWED UP  
WITH ANY OF HIS MEDICAL  
TEAM BUT HAS AN  
APPOINTMENT SCHEDULED  
WITH PALLIATIVE CARE ON  
06APR2021. HE WAS  
INSTRUCTED TO UPDATE THE  
STUDY TEAM AFTER HIS  
PALLIATIVE CARE  
APPOINTMENT.

---

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

---

---

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Feb 2021 02:38:31

Generated On: 10 Jun 2021 09:13:13

---

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

Yes ☒

No ☐

---

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

---

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication XARELTO

Prophylaxis Yes ☐  
No ☒

Indication HISTORY OF BLOOD CLOTS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

358 of 2395

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication MIRTAZAPINE

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

360 of 2395

EAB) (1725)

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

	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"/>

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

362 of 2395

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication TRINTELLIX

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

364 of 2395

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication DOXAZUSIN

Prophylaxis Yes ☐  
No ☒

Indication PROSTATE ISSUE

Dose per administration 2

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)

366 of 2395

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication NATURE MADE SUPER B  
COMPLEX

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

368 of 2395

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

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

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication FOLATE

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

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)

370 of 2395

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication ONDANSETRON ODT

Prophylaxis Yes ☐  
No ☒

Indication NAUSEA R/T OPDIVO

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

372 of 2395

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

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)

374 of 2395

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

	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 1980	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication OPDIVO

Prophylaxis Yes ☐  
No ☒

Indication RENAL CELL CARCINOMA

Dose per administration UNK

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

If dose unit is Other, specify UNK

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

376 of 2395

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 2019		
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"/>

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication LAMOTRIGINE

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

378 of 2395

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

	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)		08 SEP 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"/>

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication SPIRIVA

Prophylaxis Yes ☐  
No ☒

Indication FATIGUE RELATED TO  
SHORTNESS OF BREATH POST  
METASTATIC RENAL CELL  
CARCINOMA

Dose per administration 18

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

380 of 2395

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication NAUSEA, MED EXPOSURE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

382 of 2395

EAB) (1725)

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

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



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication LAMOTRIGINE

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

384 of 2395

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication GUAIFENESIN (EXTENDED RELEASE)

Prophylaxis Yes ☒  
No ☐

Indication COUGH

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

386 of 2395

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

	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)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication VITAMIN B1

Prophylaxis Yes ☒  
No ☐

Indication RELAPSE OF RENAL CELL  
CARCINOMA METASTASIZED  
TO HIS LUNGS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

388 of 2395

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

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

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication BENZONATATE

Prophylaxis Yes ☐  
No ☒

Indication COUGH

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

390 of 2395

EAB) (1725)

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

	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)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication RELAPSE OF RENAL CELL  
CARCINOMA METASTASIZED  
TO HIS LUNGS

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

392 of 2395

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

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

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication POSSIBLE RELAPSE OF RENAL  
CELL CARCINOMA  
METASTASIZED TO HIS LUNGS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

394 of 2395

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

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

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐  
No ☒

Indication RELAPSE OF RENAL CELL  
CARCINOMA METASTASIZED  
TO HIS LUNGS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

396 of 2395

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

	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)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

Name of Medication CHLORDIAZEPOXIDE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY RELATED TO  
RELAPSE OF RENAL CELL  
CARCINOMA METASTASIZED  
TO HIS LUNGS

Dose per administration 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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

398 of 2395

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 08 Apr 2021 23:54:01

Generated On: 10 Jun 2021 09:13:13

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



US3642076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Mar 2021 21:17:05

Generated On: 10 Jun 2021 09:13:13

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3642076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 03 Apr 2021 23:27:56

Generated On: 10 Jun 2021 09:13:13

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 FEB 2021	CT SCAN OF ABDOMEN AND THE BRAIN	Diagnostic	

US3642076

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:13:13

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

US3642076

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:13:13

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 ☐

US3642076

Folder: SAE USA-US109-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 19 Apr 2021 18:02:00

Generated On: 10 Jun 2021 09:13:13

SAEID	USA-US109-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3642076

Folder: SAE USA-US109-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Apr 2021 18:02:00

Generated On: 10 Jun 2021 09:13:13

SAEID	USA-US109-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	02/MAR/2021 09:18
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

US3642076

Folder: SAE USA-US109-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Apr 2021 18:02:00

Generated On: 10 Jun 2021 09:13:13

SAEID	USA-US109-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	15/MAR/2021 09:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3642076

Folder: SAE USA-US109-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Apr 2021 18:02:00

Generated On: 10 Jun 2021 09:13:13

SAEID	USA-US109-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	16/MAR/2021 09:27
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



US3642076

Folder: SAE USA-US109-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Apr 2021 18:02:00

Generated On: 10 Jun 2021 09:13:13

SAEID	USA-US109-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	07/APR/2021 09:35
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

US3642076

Folder: SAE USA-US109-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 19 Apr 2021 18:02:00

Generated On: 10 Jun 2021 09:13:13

SAEID	USA-US109-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	16/APR/2021 08:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3642076

Folder: SAE USA-US109-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Data signed: (b) (4) 19 Apr 2021 18:02:00

Generated On: 10 Jun 2021 09:13:13

SAEID	USA-US109-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	16/APR/2021 11:28
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

US3642076 (Prod: University of California San Diego)

**US3642076**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:13:13**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'US3642076'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 23:34:23

**US3642076**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:09

**US3642076**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '01 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 23:34:24

US3642076

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Clinic (Clinic)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:09



**US3642076**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'SCRN'	System	02 Sep 2020 00:15:09

**US3642076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:13**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 23:34:25

**US3642076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:13**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '65'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:34

**US3642076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:13**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'YEARS'	System	02 Sep 2020 00:15:34

**US3642076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:13**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered '65'	System	02 Sep 2020 00:15:52

**US3642076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:13**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Male (M)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:34

**US3642076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:13**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:34

**US3642076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:13**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'I'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:34



**US3642076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:13**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:34

**US3642076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:13**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:34

**US3642076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:13**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:34

**US3642076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:13**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:34

**US3642076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:13**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:34

**US3642076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:13**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:34

**US3642076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:13**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:34

**US3642076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:13**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:34



**US3642076**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:13**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '1 Sep 2020'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:52

**US3642076**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'Sep 2020'	System	02 Sep 2020 00:15:52

**US3642076**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered '2020'	System	02 Sep 2020 00:15:52

**US3642076**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:13**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Amendment 3 (3)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:52

US3642076

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:52

**US3642076**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:52

**US3642076**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:13**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:52

**US3642076**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:13**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:52



**US3642076**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:13**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 23:34:24

**US3642076**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:13**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'I'	System	02 Sep 2020 00:15:57

US3642076

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:15:57

**US3642076**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:13:13**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 16:42:25

US3642076

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User coded data point as SOC: Vascular disorders, HLT: Embolism and thrombosis, HLT: Non-site specific embolism and thrombosis, PT: Thrombosis, LLT: Clot blood - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:59:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:59:25
Data point term sent to Coder	System	05 Oct 2020 15:47:14
Datapoint queued for coding (5084669).	System	05 Oct 2020 15:46:41
User entered 'bLOOD CLOTS HISTORY' reason for change: Data Entry Error	Son Do (b) (4)	23 Sep 2020 16:43:01
Data point term sent to Coder	System	23 Sep 2020 16:42:57
User entered 'cloud clots history'	Son Do (b) (4)	23 Sep 2020 16:42:45

**US3642076**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'UN UNK 2015'	Son Do (b) (4)	23 Sep 2020 16:42:45

**US3642076**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	23 Sep 2020 16:42:45

**US3642076**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 16:42:45



**US3642076**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Son Do (b) (4)	23 Sep 2020 16:42:45

**US3642076**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	23 Sep 2020 16:42:45

**US3642076**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'Jan 2015'	System	23 Sep 2020 16:42:45

**US3642076**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered '2015'	System	23 Sep 2020 16:42:45

**US3642076**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered empty.	System	23 Sep 2020 16:42:45

**US3642076**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered empty.	System	23 Sep 2020 16:42:45

US3642076

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 16:44:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 16:44:36
Data point term sent to Coder	System	23 Sep 2020 16:43:59
User entered 'hyperlipidemia'	Son Do (b) (4)	23 Sep 2020 16:43:22

**US3642076**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'UN UNK 2018'	Son Do (b) (4)	23 Sep 2020 16:43:22



**US3642076**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	23 Sep 2020 16:43:22

**US3642076**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 16:43:22

**US3642076**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Son Do (b) (4)	23 Sep 2020 16:43:22

**US3642076**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	23 Sep 2020 16:43:22

**US3642076**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'Jan 2018'	System	23 Sep 2020 16:43:22

**US3642076**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered '2018'	System	23 Sep 2020 16:43:22

**US3642076**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered empty.	System	23 Sep 2020 16:43:22

**US3642076**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered empty.	System	23 Sep 2020 16:43:22



US3642076

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 04:32:40
Query 'Per DM CLR: Please note that there is no Con Megan Loughran Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'patient does not report taking any diabetes medications; data are correct' (Site from DM).	(b) (4) (b) (4)	27 Oct 2020 22:28:37
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 16:09:52
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) (b) (4)	23 Sep 2020 16:44:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 16:44:35
Data point term sent to Coder	System	23 Sep 2020 16:44:00
User entered 'type 2 diabetes'	Son Do (b) (4)	23 Sep 2020 16:43:41

**US3642076**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'UN UNK 2015'	Son Do (b) (4)	23 Sep 2020 16:43:41

**US3642076**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	23 Sep 2020 16:43:41

**US3642076**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 16:43:41

**US3642076**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Son Do (b) (4)	23 Sep 2020 16:43:41

**US3642076**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	23 Sep 2020 16:43:41

**US3642076**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'Jan 2015'	System	23 Sep 2020 16:43:41

**US3642076**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered '2015'	System	23 Sep 2020 16:43:41



**US3642076**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered empty.	System	23 Sep 2020 16:43:41

**US3642076**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered empty.	System	23 Sep 2020 16:43:41

US3642076

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatic disorder, LLT: Prostatic disorder - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 08:17:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 08:17:24
Data point term sent to Coder	System	23 Sep 2020 16:44:00
User entered 'prostate issue'	Son Do (b) (4)	23 Sep 2020 16:43:56

**US3642076**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'UN UNK 2010'	Son Do (b) (4)	23 Sep 2020 16:43:56

**US3642076**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	23 Sep 2020 16:43:56

**US3642076**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 16:43:56

**US3642076**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Son Do (b) (4)	23 Sep 2020 16:43:56

**US3642076**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	23 Sep 2020 16:43:56



**US3642076**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'Jan 2010'	System	23 Sep 2020 16:43:56

**US3642076**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered '2010'	System	23 Sep 2020 16:43:56

**US3642076**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered empty.	System	23 Sep 2020 16:43:56

**US3642076**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered empty.	System	23 Sep 2020 16:43:56

US3642076

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User coded data point as SOC: Psychiatric disorders, HLGTT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 15:13:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 15:13:53
Data point term sent to Coder	System	30 Oct 2020 15:13:23
User entered 'depression'	Son Do (b) (4)	30 Oct 2020 15:13:22

**US3642076**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'UN UNK 1980'	Son Do (b) (4)	30 Oct 2020 15:13:22

**US3642076**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	30 Oct 2020 15:13:22

**US3642076**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	30 Oct 2020 15:13:22



**US3642076**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Son Do (b) (4)	30 Oct 2020 15:13:22

**US3642076**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	30 Oct 2020 15:13:22

**US3642076**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'Jan 1980'	System	30 Oct 2020 15:13:22

**US3642076**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered '1980'	System	30 Oct 2020 15:13:22

**US3642076**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered empty.	System	30 Oct 2020 15:13:22

**US3642076**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered empty.	System	30 Oct 2020 15:13:22

US3642076

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 15:14:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 15:14:53
Data point term sent to Coder	System	30 Oct 2020 15:14:24
User entered 'fatigue'	Son Do (b) (4)	30 Oct 2020 15:13:52

**US3642076**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'UN UNK 2015'	Son Do (b) (4)	30 Oct 2020 15:13:52



**US3642076**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	30 Oct 2020 15:13:52

**US3642076**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:13:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	30 Oct 2020 15:13:52

**US3642076**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Son Do (b) (4)	30 Oct 2020 15:13:52

**US3642076**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:13:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	30 Oct 2020 15:13:52

**US3642076**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'Jan 2015'	System	30 Oct 2020 15:13:52

**US3642076**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered '2015'	System	30 Oct 2020 15:13:52

**US3642076**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered empty.	System	30 Oct 2020 15:13:52

**US3642076**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered empty.	System	30 Oct 2020 15:13:52



US3642076

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 16:12:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 16:12:55
Data point term sent to Coder	System	30 Oct 2020 15:14:24
User entered 'periprerel neuropathy'	Son Do (b) (4)	30 Oct 2020 15:14:12

**US3642076**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'UN UNK 2017'	Son Do (b) (4)	30 Oct 2020 15:14:12

**US3642076**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	30 Oct 2020 15:14:12

**US3642076**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	30 Oct 2020 15:14:12

**US3642076**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Son Do (b) (4)	30 Oct 2020 15:14:12

**US3642076**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	30 Oct 2020 15:14:12

**US3642076**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'Jan 2017'	System	30 Oct 2020 15:14:12

**US3642076**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered '2017'	System	30 Oct 2020 15:14:12



**US3642076**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered empty.	System	30 Oct 2020 15:14:12

**US3642076**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered empty.	System	30 Oct 2020 15:14:12

US3642076

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Renal and urinary tract neoplasms malignant and unspecified, HLT: Renal neoplasms malignant, PT: Renal cell carcinoma, LLT: Renal cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 23:13:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 23:13:28
Data point term sent to Coder	System	04 Feb 2021 23:12:58
User entered 'RENAL CELL CARCINOMA'	Colleen McLellan (b) (4)	04 Feb 2021 23:12:21

**US3642076**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'UN UNK 2015'	(b) (4) Colleen McLellan (b) (4)	04 Feb 2021 23:12:21

**US3642076**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	(b) (4) Colleen McLellan (b) (4)	04 Feb 2021 23:12:21

**US3642076**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:13:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	(b) (4) Colleen McLellan (b) (4)	04 Feb 2021 23:12:21

**US3642076**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'UN UNK 2019'	(b) (4) Colleen McLellan (b) (4)	04 Feb 2021 23:12:21

**US3642076**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:13:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	(b) (4) Colleen McLellan (b) (4)	04 Feb 2021 23:12:21



**US3642076**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'Jan 2015'	System	04 Feb 2021 23:12:21

**US3642076**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered '2015'	System	04 Feb 2021 23:12:21

**US3642076**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'Jan 2019'	System	04 Feb 2021 23:12:21

**US3642076**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered '2019'	System	04 Feb 2021 23:12:21

US3642076

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:13:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 23:19:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 23:19:34
Data point term sent to Coder	System	04 Feb 2021 23:18:59
User entered 'HEADACHES'	Colleen McLellan (b) (4)	04 Feb 2021 23:18:33

**US3642076**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'UN UNK 1980'	(b) (4) Colleen McLellan (b) (4)	04 Feb 2021 23:18:33

**US3642076**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	(b) (4) Colleen McLellan (b) (4)	04 Feb 2021 23:18:33

**US3642076**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	(b) (4) Colleen McLellan (b) (4)	04 Feb 2021 23:18:33



**US3642076**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:13**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	(b) (4) Colleen McLellan (b) (4)	04 Feb 2021 23:18:33

**US3642076**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	(b) (4) Colleen McLellan (b) (4)	04 Feb 2021 23:18:33

**US3642076**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'Jan 1980'	System	04 Feb 2021 23:18:33

**US3642076**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered '1980'	System	04 Feb 2021 23:18:33

**US3642076**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered empty.	System	04 Feb 2021 23:18:33

**US3642076**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered empty.	System	04 Feb 2021 23:18:33

US3642076

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:13:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:30
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 09:00:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 09:00:58
Data point term sent to Coder	System	15 Mar 2021 21:45:44
User entered 'Nausea related to Opdivo'	Nancy Tang (b) (4)	15 Mar 2021 21:45:41

**US3642076**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:30
User entered 'UN UNK 2018'	(b) (4) Nancy Tang (b) (4)	15 Mar 2021 21:45:41



**US3642076**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:30
User entered '0'	(b) (4) Nancy Tang (b) (4)	15 Mar 2021 21:45:41

**US3642076**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:13:13**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:30
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	15 Mar 2021 21:45:41

**US3642076**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:30
User entered empty.	(b) (4) Nancy Tang (b) (4)	15 Mar 2021 21:45:41

**US3642076**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:13:13**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:30
User entered '0'	(b) (4) Nancy Tang (b) (4)	15 Mar 2021 21:45:41

US3642076

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:13:13

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'Jan 2018'	System	15 Mar 2021 21:45:41

**US3642076**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered '2018'	System	15 Mar 2021 21:45:41

**US3642076**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered empty.	System	15 Mar 2021 21:45:41

**US3642076**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered empty.	System	15 Mar 2021 21:45:41



**US3642076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 16:51:34

**US3642076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '01 Sep 2020'	Son Do (b) (4)	23 Sep 2020 16:51:34

**US3642076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '15:30'	Son Do (b) (4)	23 Sep 2020 16:51:34

**US3642076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered '01 Sep 2020 15:30'	System	23 Sep 2020 16:51:34

**US3642076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '189.5' cm	(b) (4)	23 Sep 2020 16:51:34
DataPoint set to visible.	Son Do (b) (4)	02 Sep 2020 00:15:57
	System	

**US3642076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '123.5' kg	(b) (4)	
DataPoint set to visible.	Son Do (b) (4)	23 Sep 2020 16:51:34
	System	02 Sep 2020 00:15:57

**US3642076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered '34.39129'	System	23 Sep 2020 16:51:34
DataPoint set to visible.	System	02 Sep 2020 00:15:57

**US3642076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'kg/m2'	System	23 Sep 2020 16:51:34
DataPoint set to visible.	System	02 Sep 2020 00:15:57



US3642076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 15:48:33
User entered '98.3' F	Son Do (b) (4)	23 Sep 2020 16:51:34

**US3642076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty; reason for change Data Entry Error	(b) (4)	
	Son Do (b) (4)	02 Oct 2020 15:48:33
User entered 'Oral (Oral)'	Son Do (b) (4)	23 Sep 2020 16:51:34

**US3642076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Son Do (b) (4)	23 Sep 2020 16:51:34

**US3642076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 15:48:33
User entered '56'	Son Do (b) (4)	23 Sep 2020 16:51:34

**US3642076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'bpm'	System	23 Sep 2020 16:51:34

US3642076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 15:48:33
User entered '12'	Son Do (b) (4)	23 Sep 2020 16:51:34

**US3642076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'breaths/min'	System	23 Sep 2020 16:51:34

US3642076

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:13

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 15:48:33
User entered '130'	Son Do (b) (4)	23 Sep 2020 16:51:34



**US3642076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'mmHg'	System	23 Sep 2020 16:51:34

**US3642076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 15:48:33
User entered '70'	Son Do (b) (4)	23 Sep 2020 16:51:34

**US3642076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User entered 'mmHg'	System	23 Sep 2020 16:51:34

**US3642076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53

**US3642076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53

**US3642076**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:13**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 16:50:32

**US3642076**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:13**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '01 Sep 2020'	Son Do (b) (4)	23 Sep 2020 16:50:32

US3642076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:13

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:53:48



US3642076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:13

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:53:48

US3642076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:13

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:53:48

US3642076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:13

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:53:48

US3642076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:13

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:53:48

US3642076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:13

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:53:48

US3642076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:13

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:53:48

US3642076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:13

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:53:48

US3642076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:13

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:53:48



US3642076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:13

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:53:48

US3642076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:13

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:53:48

**US3642076**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:13:13**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:53:48

US3642076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Son Do (b) (4)	23 Sep 2020 16:53:48

**US3642076**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:13:13**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	23 Sep 2020 16:53:48

**US3642076**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	23 Sep 2020 16:53:48

US3642076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:13

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	23 Sep 2020 16:53:48

US3642076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:13

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	23 Sep 2020 16:53:48



US3642076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:13

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	23 Sep 2020 16:53:48

US3642076

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:13

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'I'	Son Do (b) (4)	23 Sep 2020 16:53:48

**US3642076**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:13:13**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '0'	Son Do (b) (4)	23 Sep 2020 16:53:48

**US3642076**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:13:13**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:53
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Son Do (b) (4)	23 Sep 2020 16:53:48

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:16:10

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '1 Sep 2020'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:16:10

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Clinic (Clinic)'	Megan Loughran (b) (4)	02 Sep 2020 00:16:10

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'VISIT1'	System	02 Sep 2020 00:16:10



US3642076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '01 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 23:34:27

US3642076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:13

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '189490'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 23:34:27

US3642076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:13

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 23:34:27

US3642076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:13

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	Megan Loughran (b) (4)	02 Sep 2020 00:17:19

US3642076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:13

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	Megan Loughran (b) (4)	02 Sep 2020 00:17:19

US3642076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:13

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:17:19

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:13:13**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:17:19

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:13:13**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:17:19



**US3642076**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:13:13**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:44:06
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:03:45
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:03:44

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 15:48:47
User entered '189.5' cm	Son Do (b) (4)	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:13

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 15:48:47
User entered '123.5' kg	Son Do (b) (4)	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 15:48:47
User entered '189.5' cm	Son Do (b) (4)	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:13

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 15:48:47
User entered '123.5' kg	Son Do (b) (4)	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 16:52:37

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '1 Sep 2020'	Son Do (b) (4)	23 Sep 2020 16:52:37



**US3642076**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '15:30'	Son Do (b) (4)	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered '1 Sep 2020 15:30'	System	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '98.3' F	Son Do (b) (4)	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Oral (Oral)'	Son Do (b) (4)	23 Sep 2020 16:52:37

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Son Do (b) (4)	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '56'	Son Do (b) (4)	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'bpm'	System	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '12'	Son Do (b) (4)	23 Sep 2020 16:52:37



US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'breaths/min'	System	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '130'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'mmHg'	System	23 Sep 2020 16:52:37

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '70'	Son Do (b) (4)	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'mmHg'	System	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 15:48:47
User entered '189.5' cm	Son Do (b) (4)	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:13

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 15:48:47
User entered '123.5' kg	Son Do (b) (4)	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	23 Sep 2020 16:52:37



US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '1 Sep 2020'	Son Do (b) (4)	23 Sep 2020 16:52:37

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '18:15'	Son Do (b) (4)	23 Sep 2020 16:52:37

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered '1 Sep 2020 18:15'	System	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '98.7' F	Son Do (b) (4)	23 Sep 2020 16:52:37

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Oral (Oral)'	Son Do (b) (4)	23 Sep 2020 16:52:37

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Son Do (b) (4)	23 Sep 2020 16:52:37

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '96'	Son Do (b) (4)	23 Sep 2020 16:52:37



**US3642076**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'bpm'	System	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '18'	Son Do (b) (4)	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'breaths/min'	System	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '129'	Son Do (b) (4)	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'mmHg'	System	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '90'	Son Do (b) (4)	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'mmHg'	System	23 Sep 2020 16:52:37

US3642076

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Son Do	04 Feb 2021 17:10:00
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 16:50:41



**US3642076**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:13**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty; reason for change Data Entry Error	(b) (4)	
	Son Do (b) (4)	04 Feb 2021 17:10:00
User entered '01 Sep 2020'	Son Do (b) (4)	23 Sep 2020 16:50:41

US3642076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:37:55

US3642076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:37:55

US3642076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Megan Loughran (b) (4)	02 Sep 2020 00:37:55

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:13**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 00:37:55

US3642076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '1 Sep 2020'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:37:55

US3642076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '17:34'	(b) (4) Megan Loughran (b) (4)	02 Sep 2020 00:37:55

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:13**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered '1 Sep 2020 17:34'	System	02 Sep 2020 00:37:55



US3642076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Left Arm (LEFT ARM)'	Megan Loughran (b) (4)	02 Sep 2020 00:37:55

US3642076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'ONCE'	System	02 Sep 2020 00:37:55

US3642076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 16:52:50

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:13**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '01 Sep 2020'	Son Do (b) (4)	23 Sep 2020 16:52:50

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:13**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '16:45'	Son Do (b) (4)	23 Sep 2020 16:52:50

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered '01 Sep 2020 16:45'	System	23 Sep 2020 16:52:50

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:13:13**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '01 Sep 2020'	Son Do (b) (4)	23 Sep 2020 16:53:02



**US3642076**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Son Do (b) (4)	23 Sep 2020 16:53:02

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 16:53:02

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:13**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '16:50'	Son Do (b) (4)	23 Sep 2020 16:53:02

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered '01 Sep 2020 16:50'	System	23 Sep 2020 16:53:02

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User accepted default value 'Nasopharyngeal Swab 2 Son Do (NASAL2)'	(b) (4)	23 Sep 2020 16:53:02

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:53:02

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:13**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Son Do (b) (4)	23 Sep 2020 16:53:02

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered empty.	System	23 Sep 2020 16:53:02



US3642076

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:13:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	08 Sep 2020 00:57:49

**US3642076**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'I'	System	08 Sep 2020 00:57:49

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-01T18:07:15', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1ee8b6dd-d521-474b-9b20-41d1acd1ede0' User entered 'Yes (Y)'	System	02 Sep 2020 01:07:48
	System	02 Sep 2020 01:07:48

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-01T18:07:25', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1ee8b6dd-d521-474b-9b20-41d1acd1ede0' User entered '98.7'	System	02 Sep 2020 01:07:48
	System	02 Sep 2020 01:07:48

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-01T18:07:30', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1ee8b6dd-d521-474b-9b20-41d1acd1ede0' User entered 'No (N)'	System	02 Sep 2020 01:07:48
	System	02 Sep 2020 01:07:48

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-01T18:07:43', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1ee8b6dd-d521-474b-9b20-41d1acd1ede0' User entered '01 Sep 2020 18:07'	System	02 Sep 2020 01:07:48
	System	02 Sep 2020 01:07:48

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '01 Sep 2020 17:54'	System	02 Sep 2020 00:37:55



US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '01 Sep 2020 20:24'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T10:43:50', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '9ef81a9b-8aec-49cd-8018-799eb1bf51ec' User entered 'Yes (Y)'	System	02 Sep 2020 17:44:28
	System	02 Sep 2020 17:44:28

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T10:43:59', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '9ef81a9b-8aec-49cd-8018-799eb1bf51ec' User entered '97.8'	System	02 Sep 2020 17:44:28
	System	02 Sep 2020 17:44:28

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T10:44:05', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '9ef81a9b-8aec-49cd-8018-799eb1bf51ec' User entered 'No (N)'	System	02 Sep 2020 17:44:28
	System	02 Sep 2020 17:44:28

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T10:44:23', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '9ef81a9b-8aec-49cd-8018-799eb1bf51ec' User entered '02 Sep 2020 10:44'	System	02 Sep 2020 17:44:28
	System	02 Sep 2020 17:44:28

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '01 Sep 2020 21:19'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '02 Sep 2020 11:59'	System	02 Sep 2020 00:37:55



US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 2'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:13**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T22:41:19', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '88c42966-a961-41bd-9385-2580a0583cb6' User entered 'Yes (Y)'	System	03 Sep 2020 05:41:40
	System	03 Sep 2020 05:41:40

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T22:41:27', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '88c42966-a961-41bd-9385-2580a0583cb6' User entered '98.1'	System	03 Sep 2020 05:41:40
	System	03 Sep 2020 05:41:40

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T22:41:31', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '88c42966-a961-41bd-9385-2580a0583cb6'	System	03 Sep 2020 05:41:40
User entered 'No (N)'	System	03 Sep 2020 05:41:40

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T22:41:37', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '88c42966-a961-41bd-9385-2580a0583cb6' User entered '02 Sep 2020 22:41'	System	03 Sep 2020 05:41:40
	System	03 Sep 2020 05:41:40

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '02 Sep 2020 12:00'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 3'	System	02 Sep 2020 00:37:55



US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-03T12:37:25', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '29e43fe8-6654-4c38-bd1a-4000a71f0e60' User entered 'Yes (Y)'	System	03 Sep 2020 19:37:51
	System	03 Sep 2020 19:37:51

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-03T12:37:38', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '29e43fe8-6654-4c38-bd1a-4000a71f0e60' User entered '98.8'	System	03 Sep 2020 19:37:51
	System	03 Sep 2020 19:37:51

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-03T12:37:42', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '29e43fe8-6654-4c38-bd1a-4000a71f0e60' User entered 'No (N)'	System	03 Sep 2020 19:37:51
	System	03 Sep 2020 19:37:51

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-03T12:37:48', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '29e43fe8-6654-4c38-bd1a-4000a71f0e60' User entered '03 Sep 2020 12:37'	System	03 Sep 2020 19:37:51
	System	03 Sep 2020 19:37:51

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 4'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-04T23:18:49', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8926fe69-607a-42a9-be36-234aba38840d' User entered 'Yes (Y)'	System	05 Sep 2020 06:19:21
	System	05 Sep 2020 06:19:21



US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-04T23:19:05', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8926fe69-607a-42a9-be36-234aba38840d' User entered '97.9'	System	05 Sep 2020 06:19:21
	System	05 Sep 2020 06:19:21

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-04T23:19:12', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8926fe69-607a-42a9-be36-234aba38840d' User entered 'No (N)'	System	05 Sep 2020 06:19:21
	System	05 Sep 2020 06:19:21

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-04T23:19:19', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8926fe69-607a-42a9-be36-234aba38840d' User entered '04 Sep 2020 23:19'	System	05 Sep 2020 06:19:21
	System	05 Sep 2020 06:19:21

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 5'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-05T13:03:57', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'cac9136a-8270-41d8-97f1-60cf974168b4' User entered 'Yes (Y)'	System	05 Sep 2020 20:04:22
	System	05 Sep 2020 20:04:22

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-05T13:04:03', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'cac9136a-8270-41d8-97f1-60cf974168b4' User entered '98.0'	System	05 Sep 2020 20:04:22
	System	05 Sep 2020 20:04:22



US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-05T13:04:07', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'cac9136a-8270-41d8-97f1-60cf974168b4' User entered 'No (N)'	System	05 Sep 2020 20:04:22
	System	05 Sep 2020 20:04:22

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-05T13:04:21', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'cac9136a-8270-41d8-97f1-60cf974168b4' User entered '05 Sep 2020 13:04'	System	05 Sep 2020 20:04:22
	System	05 Sep 2020 20:04:22

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 6'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-06T12:06:13', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '87c2b934-862d-42b5-a742-2c44087f4adf' User entered 'Yes (Y)'	System	06 Sep 2020 19:06:33
	System	06 Sep 2020 19:06:33

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-06T12:06:20', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '87c2b934-862d-42b5-a742-2c44087f4adf' User entered '97.7'	System	06 Sep 2020 19:06:33
	System	06 Sep 2020 19:06:33

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-06T12:06:26', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '87c2b934-862d-42b5-a742-2c44087f4adf' User entered 'No (N)'	System	06 Sep 2020 19:06:33
	System	06 Sep 2020 19:06:33



**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-06T12:06:31', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '87c2b934-862d-42b5-a742-2c44087f4adf' User entered '06 Sep 2020 12:06'	System	06 Sep 2020 19:06:33
	System	06 Sep 2020 19:06:33

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 7'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-07T12:13:06', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '64ca2811-f958-4dcb-aad0-e282cea580de' User entered 'Yes (Y)'	System	07 Sep 2020 19:13:37
	System	07 Sep 2020 19:13:37

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-07T12:13:18', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '64ca2811-f958-4dcb-aad0-e282cea580de' User entered '98.0'	System	07 Sep 2020 19:13:37
	System	07 Sep 2020 19:13:37

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-07T12:13:22', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '64ca2811-f958-4dcb-aad0-e282cea580de' User entered 'No (N)'	System	07 Sep 2020 19:13:37
	System	07 Sep 2020 19:13:37

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-07T12:13:35', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '64ca2811-f958-4dcb-aad0-e282cea580de' User entered '07 Sep 2020 12:13'	System	07 Sep 2020 19:13:37
	System	07 Sep 2020 19:13:37



**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-01T18:08:04', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'eda2764f-5e39-49c9-abf6-16624bfb8e9b' User entered 'None (1)'	System	02 Sep 2020 01:08:53
	System	02 Sep 2020 01:08:53

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-01T18:08:28', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'eda2764f-5e39-49c9-abf6-16624bf8e9b' User entered 'No (N)'	System	02 Sep 2020 01:08:53
	System	02 Sep 2020 01:08:53

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-01T18:08:34', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'eda2764f-5e39-49c9-abf6-16624bf8e9b' User entered 'No (N)'	System	02 Sep 2020 01:08:53
	System	02 Sep 2020 01:08:53

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-01T18:08:44', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'eda2764f-5e39-49c9-abf6-16624bfb8e9b' User entered 'None (1)'	System	02 Sep 2020 01:08:53
	System	02 Sep 2020 01:08:53

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-01T18:08:51', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'eda2764f-5e39-49c9-abf6-16624bfb8e9b' User entered '01 Sep 2020 18:08'	System	02 Sep 2020 01:08:53
	System	02 Sep 2020 01:08:53



**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '01 Sep 2020 17:54'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '01 Sep 2020 20:24'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T10:44:33', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '34f7dcfa-99c6-4dc2-9a20-baaa3df207d2'	System	02 Sep 2020 17:45:09
User entered 'None (1)'	System	02 Sep 2020 17:45:09

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T10:44:38', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '34f7dcfa-99c6-4dc2-9a20-baaa3df207d2' User entered 'No (N)'	System	02 Sep 2020 17:45:09
	System	02 Sep 2020 17:45:09

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T10:44:42', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '34f7dcfa-99c6-4dc2-9a20-baaa3df207d2' User entered 'No (N)'	System	02 Sep 2020 17:45:09
	System	02 Sep 2020 17:45:09

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T10:45:00', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '34f7dcfa-99c6-4dc2-9a20-baaa3df207d2'	System	02 Sep 2020 17:45:09
User entered 'None (1)'	System	02 Sep 2020 17:45:09

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T10:45:06', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '34f7dcfa-99c6-4dc2-9a20-baaa3df207d2' User entered '02 Sep 2020 10:45'	System	02 Sep 2020 17:45:09
	System	02 Sep 2020 17:45:09



**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '01 Sep 2020 21:19'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '02 Sep 2020 11:59'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 2'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T22:41:51', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '4c761c07-34f3-4a6e-8c32-f16e38794c27'	System	03 Sep 2020 05:42:18
User entered 'None (1)'	System	03 Sep 2020 05:42:18

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T22:41:55', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '4c761c07-34f3-4a6e-8c32-f16e38794c27'	System	03 Sep 2020 05:42:18
User entered 'No (N)'	System	03 Sep 2020 05:42:18

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T22:41:59', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '4c761c07-34f3-4a6e-8c32-f16e38794c27'	System	03 Sep 2020 05:42:18
User entered 'No (N)'	System	03 Sep 2020 05:42:18

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T22:42:11', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '4c761c07-34f3-4a6e-8c32-f16e38794c27'	System	03 Sep 2020 05:42:18
User entered 'None (1)'	System	03 Sep 2020 05:42:18

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T22:42:16', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '4c761c07-34f3-4a6e-8c32-f16e38794c27' User entered '02 Sep 2020 22:42'	System	03 Sep 2020 05:42:18
	System	03 Sep 2020 05:42:18



**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '02 Sep 2020 12:00'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 3'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-03T12:38:08', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'd44806c2-49eb-4943-a8c2-a0ce81a08df9' User entered 'None (1)'	System	03 Sep 2020 19:38:35
	System	03 Sep 2020 19:38:35

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-03T12:38:13', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'd44806c2-49eb-4943-a8c2-a0ce81a08df9' User entered 'No (N)'	System	03 Sep 2020 19:38:35
	System	03 Sep 2020 19:38:35

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-03T12:38:18', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'd44806c2-49eb-4943-a8c2-a0ce81a08df9' User entered 'No (N)'	System	03 Sep 2020 19:38:35
	System	03 Sep 2020 19:38:35

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-03T12:38:24', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'd44806c2-49eb-4943-a8c2-a0ce81a08df9' User entered 'None (1)'	System	03 Sep 2020 19:38:35
	System	03 Sep 2020 19:38:35

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-03T12:38:30', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'd44806c2-49eb-4943-a8c2-a0ce81a08df9' User entered '03 Sep 2020 12:38'	System	03 Sep 2020 19:38:35
	System	03 Sep 2020 19:38:35



**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 4'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-04T23:19:31', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '43816f47-9191-411c-8561-d560c63e38df' User entered 'None (1)'	System	05 Sep 2020 06:19:49
	System	05 Sep 2020 06:19:49

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-04T23:19:36', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '43816f47-9191-411c-8561-d560c63e38df' User entered 'No (N)'	System	05 Sep 2020 06:19:49
	System	05 Sep 2020 06:19:49

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-04T23:19:40', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '43816f47-9191-411c-8561-d560c63e38df' User entered 'No (N)'	System	05 Sep 2020 06:19:49
	System	05 Sep 2020 06:19:49

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-04T23:19:44', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '43816f47-9191-411c-8561-d560c63e38df' User entered 'None (1)'	System	05 Sep 2020 06:19:49
	System	05 Sep 2020 06:19:49

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-04T23:19:48', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '43816f47-9191-411c-8561-d560c63e38df' User entered '04 Sep 2020 23:19'	System	05 Sep 2020 06:19:49
	System	05 Sep 2020 06:19:49



**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 5'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-05T13:04:37', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8c00c492-a706-47cc-9d50-2b6f4ea776f8'	System	05 Sep 2020 20:04:59
User entered 'None (1)'	System	05 Sep 2020 20:04:59

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-05T13:04:41', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8c00c492-a706-47cc-9d50-2b6f4ea776f8' User entered 'No (N)'	System	05 Sep 2020 20:04:59
	System	05 Sep 2020 20:04:59

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-05T13:04:45', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8c00c492-a706-47cc-9d50-2b6f4ea776f8' User entered 'No (N)'	System	05 Sep 2020 20:04:59
	System	05 Sep 2020 20:04:59

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-05T13:04:53', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8c00c492-a706-47cc-9d50-2b6f4ea776f8' User entered 'None (1)'	System	05 Sep 2020 20:04:59
	System	05 Sep 2020 20:04:59

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-05T13:04:57', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8c00c492-a706-47cc-9d50-2b6f4ea776f8' User entered '05 Sep 2020 13:04'	System	05 Sep 2020 20:04:59
	System	05 Sep 2020 20:04:59



**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 6'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-06T12:06:38', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '2257cadb-6cc1-45dd-af54-f85975cbec57'	System	06 Sep 2020 19:06:57
User entered 'None (1)'	System	06 Sep 2020 19:06:57

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-06T12:06:42', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '2257cadb-6cc1-45dd-af54-f85975cbec57' User entered 'No (N)'	System	06 Sep 2020 19:06:57
	System	06 Sep 2020 19:06:57

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-06T12:06:46', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '2257cadb-6cc1-45dd-af54-f85975cbec57' User entered 'No (N)'	System	06 Sep 2020 19:06:57
	System	06 Sep 2020 19:06:57

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-06T12:06:52', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '2257cadb-6cc1-45dd-af54-f85975cbec57' User entered 'None (1)'	System	06 Sep 2020 19:06:57
	System	06 Sep 2020 19:06:57

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-06T12:06:55', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '2257cadb-6cc1-45dd-af54-f85975cbec57' User entered '06 Sep 2020 12:06'	System	06 Sep 2020 19:06:57
	System	06 Sep 2020 19:06:57



US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 7'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-07T12:13:54', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '84dc7a39-e155-4017-937c-e93f448d7508'	System	07 Sep 2020 19:14:16
User entered 'None (1)'	System	07 Sep 2020 19:14:16

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-07T12:13:58', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '84dc7a39-e155-4017-937c-e93f448d7508'	System	07 Sep 2020 19:14:16
User entered 'No (N)'	System	07 Sep 2020 19:14:16

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-07T12:14:01', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '84dc7a39-e155-4017-937c-e93f448d7508' User entered 'No (N)'	System	07 Sep 2020 19:14:16
	System	07 Sep 2020 19:14:16

US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-07T12:14:05', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '84dc7a39-e155-4017-937c-e93f448d7508'	System	07 Sep 2020 19:14:16
User entered 'None (1)'	System	07 Sep 2020 19:14:16

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-07T12:14:12', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '84dc7a39-e155-4017-937c-e93f448d7508' User entered '07 Sep 2020 12:14'	System	07 Sep 2020 19:14:16
	System	07 Sep 2020 19:14:16



US3642076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-01T18:09:00', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8770840f-60ef-44ff-93bd-a9fb089fffe0' User entered 'None (0)'	System	02 Sep 2020 01:09:59
	System	02 Sep 2020 01:09:59

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-01T18:09:18', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8770840f-60ef-44ff-93bd-a9fb089fffe0' User entered 'None (0)'	System	02 Sep 2020 01:09:59
	System	02 Sep 2020 01:09:59

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-01T18:09:24', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8770840f-60ef-44ff-93bd-a9fb089fffe0' User entered 'None (0)'	System	02 Sep 2020 01:09:59
	System	02 Sep 2020 01:09:59

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-01T18:09:32', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8770840f-60ef-44ff-93bd-a9fb089fffe0' User entered 'None (0)'	System	02 Sep 2020 01:09:59
	System	02 Sep 2020 01:09:59

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-01T18:09:38', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8770840f-60ef-44ff-93bd-a9fb089fffe0' User entered 'None (0)'	System	02 Sep 2020 01:09:59
	System	02 Sep 2020 01:09:59



**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-01T18:09:44', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8770840f-60ef-44ff-93bd-a9fb089fffe0' User entered 'None (0)'	System	02 Sep 2020 01:09:59
	System	02 Sep 2020 01:09:59

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

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)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-01T18:09:50', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8770840f-60ef-44ff-93bd-a9fb089fffe0' User entered 'No (N)'	System	02 Sep 2020 01:09:59
	System	02 Sep 2020 01:09:59

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-01T18:09:56', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8770840f-60ef-44ff-93bd-a9fb089fffe0' User entered '01 Sep 2020 18:09'	System	02 Sep 2020 01:09:59
	System	02 Sep 2020 01:09:59

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '01 Sep 2020 17:54'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '01 Sep 2020 20:24'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T10:45:15', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '2cc82f8e-e188-4f82-b392-4e7e97f9c7dc' User entered 'None (0)'	System	02 Sep 2020 17:46:00
	System	02 Sep 2020 17:46:00

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T10:45:23', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '2cc82f8e-e188-4f82-b392-4e7e97f9c7dc' User entered 'None (0)'	System	02 Sep 2020 17:46:00
	System	02 Sep 2020 17:46:00



US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T10:45:27', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '2cc82f8e-e188-4f82-b392-4e7e97f9c7dc' User entered 'None (0)'	System	02 Sep 2020 17:46:00
	System	02 Sep 2020 17:46:00

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T10:45:33', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '2cc82f8e-e188-4f82-b392-4e7e97f9c7dc' User entered 'None (0)'	System	02 Sep 2020 17:46:00
	System	02 Sep 2020 17:46:00

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T10:45:39', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '2cc82f8e-e188-4f82-b392-4e7e97f9c7dc' User entered 'None (0)'	System	02 Sep 2020 17:46:00
	System	02 Sep 2020 17:46:00

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T10:45:44', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '2cc82f8e-e188-4f82-b392-4e7e97f9c7dc' User entered 'None (0)'	System	02 Sep 2020 17:46:00
	System	02 Sep 2020 17:46:00

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

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)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T10:45:51', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '2cc82f8e-e188-4f82-b392-4e7e97f9c7dc' User entered 'No (N)'	System	02 Sep 2020 17:46:00
	System	02 Sep 2020 17:46:00

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T10:45:58', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '2cc82f8e-e188-4f82-b392-4e7e97f9c7dc' User entered '02 Sep 2020 10:45'	System	02 Sep 2020 17:46:00
	System	02 Sep 2020 17:46:00

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '01 Sep 2020 21:19'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '02 Sep 2020 11:59'	System	02 Sep 2020 00:37:55



US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 2'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T22:42:22', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '61444fd0-8513-4a72-b273-ccb8a878b7d2' User entered 'None (0)'	System	03 Sep 2020 05:42:56
	System	03 Sep 2020 05:42:56

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:13**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T22:42:28', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '61444fd0-8513-4a72-b273-ccb8a878b7d2' User entered 'None (0)'	System	03 Sep 2020 05:42:56
	System	03 Sep 2020 05:42:56

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T22:42:31', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '61444fd0-8513-4a72-b273-ccb8a878b7d2' User entered 'None (0)'	System	03 Sep 2020 05:42:56
	System	03 Sep 2020 05:42:56

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T22:42:36', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '61444fd0-8513-4a72-b273-ccb8a878b7d2' User entered 'None (0)'	System	03 Sep 2020 05:42:56
	System	03 Sep 2020 05:42:56

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T22:42:39', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '61444fd0-8513-4a72-b273-ccb8a878b7d2' User entered 'None (0)'	System	03 Sep 2020 05:42:56
	System	03 Sep 2020 05:42:56

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T22:42:43', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '61444fd0-8513-4a72-b273-ccb8a878b7d2' User entered 'None (0)'	System	03 Sep 2020 05:42:56
	System	03 Sep 2020 05:42:56

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:13

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)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T22:42:49', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '61444fd0-8513-4a72-b273-ccb8a878b7d2' User entered 'No (N)'	System	03 Sep 2020 05:42:56
	System	03 Sep 2020 05:42:56



**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-02T22:42:52', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '61444fd0-8513-4a72-b273-ccb8a878b7d2' User entered '02 Sep 2020 22:42'	System	03 Sep 2020 05:42:56
	System	03 Sep 2020 05:42:56

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '02 Sep 2020 12:00'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 3'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-03T12:38:37', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c4d68a0a-a828-41c8-ab12-8c0636b4c21f' User entered 'None (0)'	System	03 Sep 2020 19:39:13
	System	03 Sep 2020 19:39:13

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-03T12:38:41', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c4d68a0a-a828-41c8-ab12-8c0636b4c21f' User entered 'None (0)'	System	03 Sep 2020 19:39:13
	System	03 Sep 2020 19:39:13

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-03T12:38:45', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c4d68a0a-a828-41c8-ab12-8c0636b4c21f' User entered 'None (0)'	System	03 Sep 2020 19:39:13
	System	03 Sep 2020 19:39:13

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-03T12:38:49', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c4d68a0a-a828-41c8-ab12-8c0636b4c21f' User entered 'None (0)'	System	03 Sep 2020 19:39:13
	System	03 Sep 2020 19:39:13



**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-03T12:38:57', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c4d68a0a-a828-41c8-ab12-8c0636b4c21f' User entered 'None (0)'	System	03 Sep 2020 19:39:13
	System	03 Sep 2020 19:39:13

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-03T12:39:00', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c4d68a0a-a828-41c8-ab12-8c0636b4c21f' User entered 'None (0)'	System	03 Sep 2020 19:39:13
	System	03 Sep 2020 19:39:13

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:13

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)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-03T12:39:06', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c4d68a0a-a828-41c8-ab12-8c0636b4c21f' User entered 'No (N)'	System	03 Sep 2020 19:39:13
	System	03 Sep 2020 19:39:13

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-03T12:39:10', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c4d68a0a-a828-41c8-ab12-8c0636b4c21f' User entered '03 Sep 2020 12:39'	System	03 Sep 2020 19:39:13
	System	03 Sep 2020 19:39:13

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 4'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-04T23:19:53', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1f9786a2-71f2-4601-b0bc-17b418867655' User entered 'None (0)'	System	05 Sep 2020 06:20:37
	System	05 Sep 2020 06:20:37



**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:13**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-04T23:19:58', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1f9786a2-71f2-4601-b0bc-17b418867655' User entered 'None (0)'	System	05 Sep 2020 06:20:37
	System	05 Sep 2020 06:20:37

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-04T23:20:04', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1f9786a2-71f2-4601-b0bc-17b418867655' User entered 'None (0)'	System	05 Sep 2020 06:20:37
	System	05 Sep 2020 06:20:37

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-04T23:20:17', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1f9786a2-71f2-4601-b0bc-17b418867655' User entered 'None (0)'	System	05 Sep 2020 06:20:37
	System	05 Sep 2020 06:20:37

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-04T23:20:23', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1f9786a2-71f2-4601-b0bc-17b418867655' User entered 'None (0)'	System	05 Sep 2020 06:20:37
	System	05 Sep 2020 06:20:37

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-04T23:20:26', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1f9786a2-71f2-4601-b0bc-17b418867655' User entered 'None (0)'	System	05 Sep 2020 06:20:37
	System	05 Sep 2020 06:20:37

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:13

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)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-04T23:20:31', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1f9786a2-71f2-4601-b0bc-17b418867655' User entered 'No (N)'	System	05 Sep 2020 06:20:37
	System	05 Sep 2020 06:20:37

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-04T23:20:35', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1f9786a2-71f2-4601-b0bc-17b418867655' User entered '04 Sep 2020 23:20'	System	05 Sep 2020 06:20:37
	System	05 Sep 2020 06:20:37

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 00:37:55



**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 5'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-05T13:05:05', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '0d5c1b19-ca77-45cb-8aeb-8961f1500a35' User entered 'None (0)'	System	05 Sep 2020 20:05:39
	System	05 Sep 2020 20:05:39

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-05T13:05:09', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '0d5c1b19-ca77-45cb-8aeb-8961f1500a35' User entered 'None (0)'	System	05 Sep 2020 20:05:39
	System	05 Sep 2020 20:05:39

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-05T13:05:14', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '0d5c1b19-ca77-45cb-8aeb-8961f1500a35' User entered 'None (0)'	System	05 Sep 2020 20:05:39
	System	05 Sep 2020 20:05:39

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-05T13:05:18', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '0d5c1b19-ca77-45cb-8aeb-8961f1500a35' User entered 'None (0)'	System	05 Sep 2020 20:05:39
	System	05 Sep 2020 20:05:39

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-05T13:05:22', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '0d5c1b19-ca77-45cb-8aeb-8961f1500a35' User entered 'None (0)'	System	05 Sep 2020 20:05:39
	System	05 Sep 2020 20:05:39

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-05T13:05:26', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '0d5c1b19-ca77-45cb-8aeb-8961f1500a35' User entered 'None (0)'	System	05 Sep 2020 20:05:39
	System	05 Sep 2020 20:05:39



US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:13

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)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-05T13:05:32', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '0d5c1b19-ca77-45cb-8aeb-8961f1500a35' User entered 'No (N)'	System	05 Sep 2020 20:05:39
	System	05 Sep 2020 20:05:39

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-05T13:05:36', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '0d5c1b19-ca77-45cb-8aeb-8961f1500a35' User entered '05 Sep 2020 13:05'	System	05 Sep 2020 20:05:39
	System	05 Sep 2020 20:05:39

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 6'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-06T12:07:00', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1f71d9e2-bec6-469d-895e-9138fb2b5fbd' User entered 'None (0)'	System	06 Sep 2020 19:07:38
	System	06 Sep 2020 19:07:38

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-06T12:07:04', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1f71d9e2-bec6-469d-895e-9138fb2b5fbd' User entered 'None (0)'	System	06 Sep 2020 19:07:38
	System	06 Sep 2020 19:07:38

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-06T12:07:10', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1f71d9e2-bec6-469d-895e-9138fb2b5fbd' User entered 'None (0)'	System	06 Sep 2020 19:07:38
	System	06 Sep 2020 19:07:38



US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-06T12:07:17', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1f71d9e2-bec6-469d-895e-9138fb2b5fbd' User entered 'None (0)'	System	06 Sep 2020 19:07:38
	System	06 Sep 2020 19:07:38

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-06T12:07:21', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1f71d9e2-bec6-469d-895e-9138fb2b5fbd' User entered 'None (0)'	System	06 Sep 2020 19:07:38
	System	06 Sep 2020 19:07:38

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-06T12:07:24', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1f71d9e2-bec6-469d-895e-9138fb2b5fbd' User entered 'None (0)'	System	06 Sep 2020 19:07:38
	System	06 Sep 2020 19:07:38

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:13

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)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-06T12:07:29', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1f71d9e2-bec6-469d-895e-9138fb2b5fbd' User entered 'No (N)'	System	06 Sep 2020 19:07:38
	System	06 Sep 2020 19:07:38

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-06T12:07:33', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1f71d9e2-bec6-469d-895e-9138fb2b5fbd' User entered '06 Sep 2020 12:07'	System	06 Sep 2020 19:07:38
	System	06 Sep 2020 19:07:38

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 00:37:55

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 7'	System	02 Sep 2020 00:37:55



US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-07T12:14:22', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '3f5ab83f-c2b9-4871-bf24-4eea15c1154a' User entered 'None (0)'	System	07 Sep 2020 19:15:01
	System	07 Sep 2020 19:15:01

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-07T12:14:26', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '3f5ab83f-c2b9-4871-bf24-4eea15c1154a' User entered 'None (0)'	System	07 Sep 2020 19:15:01
	System	07 Sep 2020 19:15:01

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-07T12:14:30', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '3f5ab83f-c2b9-4871-bf24-4eea15c1154a' User entered 'None (0)'	System	07 Sep 2020 19:15:01
	System	07 Sep 2020 19:15:01

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-07T12:14:33', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '3f5ab83f-c2b9-4871-bf24-4eea15c1154a' User entered 'None (0)'	System	07 Sep 2020 19:15:01
	System	07 Sep 2020 19:15:01

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-07T12:14:37', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '3f5ab83f-c2b9-4871-bf24-4eea15c1154a' User entered 'None (0)'	System	07 Sep 2020 19:15:01
	System	07 Sep 2020 19:15:01

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-07T12:14:41', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '3f5ab83f-c2b9-4871-bf24-4eea15c1154a' User entered 'None (0)'	System	07 Sep 2020 19:15:01
	System	07 Sep 2020 19:15:01

US3642076

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:13

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)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-07T12:14:44', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '3f5ab83f-c2b9-4871-bf24-4eea15c1154a' User entered 'No (N)'	System	07 Sep 2020 19:15:01
	System	07 Sep 2020 19:15:01

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-07T12:14:57', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '3f5ab83f-c2b9-4871-bf24-4eea15c1154a' User entered '07 Sep 2020 12:14'	System	07 Sep 2020 19:15:01
	System	07 Sep 2020 19:15:01



**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 00:37:55

**US3642076**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	09 Sep 2020 00:47:08

**US3642076**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '08 Sep 2020'	(b) (4) Nancy Tang (b) (4)	09 Sep 2020 00:47:08

**US3642076**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nancy Tang (b) (4)	09 Sep 2020 00:47:08

US3642076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	(b) (4) Nancy Tang (b) (4)	09 Sep 2020 00:47:08

**US3642076**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	09 Sep 2020 00:47:12

**US3642076**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'I'	System	09 Sep 2020 00:47:12



**US3642076**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	17 Sep 2020 16:59:54

**US3642076**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '17 Sep 2020'	Colleen McLellan (b) (4)	17 Sep 2020 16:59:54

US3642076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Contact Made (CONTACT MADE)'	Colleen McLellan (b) (4)	17 Sep 2020 16:59:54

US3642076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Colleen McLellan (b) (4)	17 Sep 2020 16:59:54

**US3642076**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	17 Sep 2020 16:59:58

**US3642076**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'I'	System	17 Sep 2020 16:59:58

**US3642076**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	23 Sep 2020 19:33:57

**US3642076**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '23 Sep 2020'	Colleen McLellan (b) (4)	23 Sep 2020 19:33:57



US3642076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Contact Made (CONTACT MADE)'	Colleen McLellan (b) (4)	23 Sep 2020 19:33:57

**US3642076**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Colleen McLellan (b) (4)	23 Sep 2020 19:33:57

US3642076

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	23 Sep 2020 19:34:01

**US3642076**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'I'	System	23 Sep 2020 19:34:01

**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	30 Sep 2020 20:43:01

US3642076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:13:13

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 30-Sep-2020 is reported under Visit 2 Day 29 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 01:36:35
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 30-Sep-2020 is reported under Visit 2 Day 29 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify. ' answered with 'swab collection information added' (Site from DM).	Megan Loughran (b) (4) (b) (4)	27 Oct 2020 22:29:29
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 30-Sep-2020 is reported under Visit 2 Day 29 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 10:58:35
User entered '30 Sep 2020'	Megan Loughran (b) (4) (b) (4)	30 Sep 2020 20:43:01

US3642076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Clinic (Clinic)'	(b) (4) Megan Loughran (b) (4)	30 Sep 2020 20:43:01

**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'VISIT2'	System	30 Sep 2020 20:43:01



US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	02 Oct 2020 15:49:48

**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '30 Sep 2020'	Son Do (b) (4)	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '13:26'	Son Do (b) (4)	02 Oct 2020 15:49:48

**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered '30 Sep 2020 13:26'	System	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '97' F	Son Do (b) (4)	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Oral (Oral)'	Son Do (b) (4)	02 Oct 2020 15:49:48

**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Son Do (b) (4)	02 Oct 2020 15:49:48



**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '96'	Son Do (b) (4)	02 Oct 2020 15:49:48

**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'bpm'	System	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '17'	Son Do (b) (4)	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'breaths/min'	System	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '142'	Son Do (b) (4)	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'mmHg'	System	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '84'	Son Do (b) (4)	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'mmHg'	System	02 Oct 2020 15:49:48



US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '30 Sep 2020'	Son Do (b) (4)	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '15:06'	Son Do (b) (4)	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered '30 Sep 2020 15:06'	System	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '97.7' F	Son Do (b) (4)	02 Oct 2020 15:49:48

**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Oral (Oral)'	Son Do (b) (4)	02 Oct 2020 15:49:48

**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Son Do (b) (4)	02 Oct 2020 15:49:48



US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '99'	Son Do (b) (4)	02 Oct 2020 15:49:48

**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'bpm'	System	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '17'	Son Do (b) (4)	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'breaths/min'	System	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '133'	Son Do (b) (4)	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'mmHg'	System	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '83'	Son Do (b) (4)	02 Oct 2020 15:49:48

US3642076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'mmHg'	System	02 Oct 2020 15:49:48



**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:13**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	02 Oct 2020 15:49:56

US3642076

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:13

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '30 Sep 2020'	Son Do (b) (4)	02 Oct 2020 15:49:56

US3642076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	30 Sep 2020 21:42:36

US3642076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	(b) (4) Megan Loughran (b) (4)	30 Sep 2020 21:42:36

US3642076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Megan Loughran (b) (4)	30 Sep 2020 21:42:36

US3642076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 21:42:36

US3642076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '30 Sep 2020'	(b) (4) Megan Loughran (b) (4)	30 Sep 2020 21:42:36

US3642076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '14:35'	(b) (4) Megan Loughran (b) (4)	30 Sep 2020 21:42:36



US3642076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered '30 Sep 2020 14:35'	System	30 Sep 2020 21:42:36

US3642076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Left Arm (LEFT ARM)'	(b) (4) Megan Loughran (b) (4)	30 Sep 2020 21:42:36

US3642076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'ONCE'	System	30 Sep 2020 21:42:36

US3642076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 21:42:36

US3642076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	02 Oct 2020 15:50:15

US3642076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '30 Sep 2020'	Son Do (b) (4)	02 Oct 2020 15:50:15

**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:13**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '13:50'	Son Do (b) (4)	02 Oct 2020 15:50:15

**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered '30 Sep 2020 13:50'	System	02 Oct 2020 15:50:15



US3642076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:13:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '30 Sep 2020'	(b) (4) Megan Loughran (b) (4)	27 Oct 2020 22:25:41

**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Megan Loughran (b) (4)	27 Oct 2020 22:25:41

**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	27 Oct 2020 22:25:41

**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:13**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '13:52'	(b) (4) Megan Loughran (b) (4)	27 Oct 2020 22:25:41

**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered '30 Sep 2020 13:52'	System	27 Oct 2020 22:25:41

**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Megan Loughran (b) (4)	27 Oct 2020 22:25:41

US3642076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:13:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	27 Oct 2020 22:25:41

**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:13**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	(b) (4) Megan Loughran (b) (4)	27 Oct 2020 22:25:41



**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered empty.	System	27 Oct 2020 22:25:41

US3642076

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	02 Oct 2020 15:50:33

**US3642076**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'I'	System	02 Oct 2020 15:50:33

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T14:57:33', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '80fbcd30-a2fa-4b1c-8076-63c85951c413' User entered 'Yes (Y)'	System	30 Sep 2020 21:58:12
	System	30 Sep 2020 21:58:12

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T14:57:56', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '80fbcd30-a2fa-4b1c-8076-63c85951c413' User entered '97.7'	System	30 Sep 2020 21:58:12
	System	30 Sep 2020 21:58:12

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T14:57:59', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '80fbcd30-a2fa-4b1c-8076-63c85951c413' User entered 'No (N)'	System	30 Sep 2020 21:58:12
	System	30 Sep 2020 21:58:12

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T14:58:07', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '80fbcd30-a2fa-4b1c-8076-63c85951c413' User entered '30 Sep 2020 14:58'	System	30 Sep 2020 21:58:12
	System	30 Sep 2020 21:58:12



**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '30 Sep 2020 14:55'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '30 Sep 2020 17:25'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T20:34:21', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'd5d98636-6ac4-40ec-98b7-d7036cbc34a7' User entered 'Yes (Y)'	System	01 Oct 2020 03:34:42
	System	01 Oct 2020 03:34:42

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T20:34:32', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'd5d98636-6ac4-40ec-98b7-d7036cbc34a7' User entered '97.7'	System	01 Oct 2020 03:34:42
	System	01 Oct 2020 03:34:42

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T20:34:36', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'd5d98636-6ac4-40ec-98b7-d7036cbc34a7'	System	01 Oct 2020 03:34:42
User entered 'No (N)'	System	01 Oct 2020 03:34:42

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T20:34:40', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'd5d98636-6ac4-40ec-98b7-d7036cbc34a7' User entered '30 Sep 2020 20:34'	System	01 Oct 2020 03:34:42
	System	01 Oct 2020 03:34:42

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '30 Sep 2020 18:20'	System	30 Sep 2020 21:42:36



US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 2'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-01T16:05:05', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'f23d240b-1871-4c7a-beec-0e88e98c60c1' User entered 'Yes (Y)'	System	01 Oct 2020 23:05:34
	System	01 Oct 2020 23:05:34

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-01T16:05:13', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'f23d240b-1871-4c7a-beec-0e88e98c60c1' User entered '97.8'	System	01 Oct 2020 23:05:34
	System	01 Oct 2020 23:05:34

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-01T16:05:21', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'f23d240b-1871-4c7a-beec-0e88e98c60c1' User entered 'No (N)'	System	01 Oct 2020 23:05:34
	System	01 Oct 2020 23:05:34

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-01T16:05:31', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'f23d240b-1871-4c7a-beec-0e88e98c60c1' User entered '01 Oct 2020 16:05'	System	01 Oct 2020 23:05:34
	System	01 Oct 2020 23:05:34

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 21:42:36



US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 3'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-02T12:07:57', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'ce31b9a6-ca2a-4519-a8ed-a130251d4639' User entered 'Yes (Y)'	System	02 Oct 2020 19:08:15
	System	02 Oct 2020 19:08:15

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-02T12:08:04', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'ce31b9a6-ca2a-4519-a8ed-a130251d4639' User entered '98.2'	System	02 Oct 2020 19:08:15
	System	02 Oct 2020 19:08:15

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-02T12:08:08', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'ce31b9a6-ca2a-4519-a8ed-a130251d4639' User entered 'No (N)'	System	02 Oct 2020 19:08:15
	System	02 Oct 2020 19:08:15

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-02T12:08:13', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'ce31b9a6-ca2a-4519-a8ed-a130251d4639' User entered '02 Oct 2020 12:08'	System	02 Oct 2020 19:08:15
	System	02 Oct 2020 19:08:15

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 4'	System	30 Sep 2020 21:42:36



US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-03T13:26:31', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '4b273437-b165-4045-9ba4-7d68a522be34'	System	03 Oct 2020 20:27:07
User entered 'Yes (Y)'	System	03 Oct 2020 20:27:07

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-03T13:26:38', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '4b273437-b165-4045-9ba4-7d68a522be34' User entered '97.5'	System	03 Oct 2020 20:27:07
	System	03 Oct 2020 20:27:07

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-03T13:26:56', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '4b273437-b165-4045-9ba4-7d68a522be34'	System	03 Oct 2020 20:27:07
User entered 'No (N)'	System	03 Oct 2020 20:27:07

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-03T13:27:04', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '4b273437-b165-4045-9ba4-7d68a522be34' User entered '03 Oct 2020 13:27'	System	03 Oct 2020 20:27:07
	System	03 Oct 2020 20:27:07

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 5'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-04T21:55:19', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '7a57bf63-df86-4a88-bd23-7ad6222a3be7' User entered 'Yes (Y)'	System	05 Oct 2020 04:55:59
	System	05 Oct 2020 04:55:59



US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-04T21:55:39', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '7a57bf63-df86-4a88-bd23-7ad6222a3be7' User entered '97.7'	System	05 Oct 2020 04:55:59
	System	05 Oct 2020 04:55:59

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-04T21:55:47', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '7a57bf63-df86-4a88-bd23-7ad6222a3be7' User entered 'No (N)'	System	05 Oct 2020 04:55:59
	System	05 Oct 2020 04:55:59

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-04T21:55:55', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '7a57bf63-df86-4a88-bd23-7ad6222a3be7' User entered '04 Oct 2020 21:55'	System	05 Oct 2020 04:55:59
	System	05 Oct 2020 04:55:59

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 6'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-05T12:04:02', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '99340a61-6549-4e24-9199-5c9e5c12f01e' User entered 'Yes (Y)'	System	05 Oct 2020 19:04:21
	System	05 Oct 2020 19:04:21

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-05T12:04:10', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '99340a61-6549-4e24-9199-5c9e5c12f01e' User entered '97.6'	System	05 Oct 2020 19:04:21
	System	05 Oct 2020 19:04:21



US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-05T12:04:14', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '99340a61-6549-4e24-9199-5c9e5c12f01e' User entered 'No (N)'	System	05 Oct 2020 19:04:21
	System	05 Oct 2020 19:04:21

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-05T12:04:20', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '99340a61-6549-4e24-9199-5c9e5c12f01e' User entered '05 Oct 2020 12:04'	System	05 Oct 2020 19:04:21
	System	05 Oct 2020 19:04:21

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 7'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-06T12:26:17', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'b1eb758e-c76b-465f-8778-651af7d322c3' User entered 'Yes (Y)'	System	06 Oct 2020 19:26:43
	System	06 Oct 2020 19:26:43

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-06T12:26:27', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'b1eb758e-c76b-465f-8778-651af7d322c3' User entered '98.3'	System	06 Oct 2020 19:26:43
	System	06 Oct 2020 19:26:43

US3642076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-06T12:26:35', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'b1eb758e-c76b-465f-8778-651af7d322c3' User entered 'No (N)'	System	06 Oct 2020 19:26:43
	System	06 Oct 2020 19:26:43



**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-06T12:26:40', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'b1eb758e-c76b-465f-8778-651af7d322c3' User entered '06 Oct 2020 12:26'	System	06 Oct 2020 19:26:43
	System	06 Oct 2020 19:26:43

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T14:58:27', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c7b851cd-850d-4a99-9ad8-9c558d3abc10' User entered 'None (1)'	System	30 Sep 2020 21:59:23
	System	30 Sep 2020 21:59:23

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T14:58:57', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c7b851cd-850d-4a99-9ad8-9c558d3abc10' User entered 'No (N)'	System	30 Sep 2020 21:59:23
	System	30 Sep 2020 21:59:23

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T14:59:04', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c7b851cd-850d-4a99-9ad8-9c558d3abc10' User entered 'No (N)'	System	30 Sep 2020 21:59:23
	System	30 Sep 2020 21:59:23

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T14:59:10', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c7b851cd-850d-4a99-9ad8-9c558d3abc10' User entered 'None (1)'	System	30 Sep 2020 21:59:23
	System	30 Sep 2020 21:59:23



**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T14:59:17', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c7b851cd-850d-4a99-9ad8-9c558d3abc10' User entered '30 Sep 2020 14:59'	System	30 Sep 2020 21:59:23
	System	30 Sep 2020 21:59:23

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '30 Sep 2020 14:55'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '30 Sep 2020 17:25'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T20:35:04', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '0e17167d-3cb0-4df3-b0fd-25ea8f284706'	System	01 Oct 2020 03:35:27
User entered 'None (1)'	System	01 Oct 2020 03:35:27

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T20:35:08', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '0e17167d-3cb0-4df3-b0fd-25ea8f284706' User entered 'No (N)'	System	01 Oct 2020 03:35:27
	System	01 Oct 2020 03:35:27

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T20:35:13', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '0e17167d-3cb0-4df3-b0fd-25ea8f284706' User entered 'No (N)'	System	01 Oct 2020 03:35:27
	System	01 Oct 2020 03:35:27

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T20:35:18', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '0e17167d-3cb0-4df3-b0fd-25ea8f284706'	System	01 Oct 2020 03:35:27
User entered 'None (1)'	System	01 Oct 2020 03:35:27



**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T20:35:24', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '0e17167d-3cb0-4df3-b0fd-25ea8f284706'	System	01 Oct 2020 03:35:27
User entered '30 Sep 2020 20:35'	System	01 Oct 2020 03:35:27

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '30 Sep 2020 18:20'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 2'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-01T16:05:56', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '989c7da2-c0f1-4474-ac67-7e70f26169e1'	System	01 Oct 2020 23:06:21
User entered 'None (1)'	System	01 Oct 2020 23:06:21

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-01T16:06:00', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '989c7da2-c0f1-4474-ac67-7e70f26169e1' User entered 'No (N)'	System	01 Oct 2020 23:06:21
	System	01 Oct 2020 23:06:21

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-01T16:06:05', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '989c7da2-c0f1-4474-ac67-7e70f26169e1' User entered 'No (N)'	System	01 Oct 2020 23:06:21
	System	01 Oct 2020 23:06:21

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-01T16:06:10', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '989c7da2-c0f1-4474-ac67-7e70f26169e1' User entered 'None (1)'	System	01 Oct 2020 23:06:21
	System	01 Oct 2020 23:06:21



**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-01T16:06:18', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '989c7da2-c0f1-4474-ac67-7e70f26169e1' User entered '01 Oct 2020 16:06'	System	01 Oct 2020 23:06:21
	System	01 Oct 2020 23:06:21

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 3'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-02T12:07:17', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'aa49c584-217e-485d-bbe6-68012af6e981'	System	02 Oct 2020 19:07:41
User entered 'None (1)'	System	02 Oct 2020 19:07:41

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-02T12:07:21', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'aa49c584-217e-485d-bbe6-68012af6e981' User entered 'No (N)'	System	02 Oct 2020 19:07:41
	System	02 Oct 2020 19:07:41

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-02T12:07:24', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'aa49c584-217e-485d-bbe6-68012af6e981' User entered 'No (N)'	System	02 Oct 2020 19:07:41
	System	02 Oct 2020 19:07:41

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-02T12:07:32', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'aa49c584-217e-485d-bbe6-68012af6e981' User entered 'None (1)'	System	02 Oct 2020 19:07:41
	System	02 Oct 2020 19:07:41



**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-02T12:07:37', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'aa49c584-217e-485d-bbe6-68012af6e981' User entered '02 Oct 2020 12:07'	System	02 Oct 2020 19:07:41
	System	02 Oct 2020 19:07:41

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 4'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-03T13:27:20', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'f3c2045e-82c9-4f3c-8260-0bb09e78fb2c' User entered 'None (1)'	System	03 Oct 2020 20:27:49
	System	03 Oct 2020 20:27:49

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-03T13:27:24', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'f3c2045e-82c9-4f3c-8260-0bb09e78fb2c' User entered 'No (N)'	System	03 Oct 2020 20:27:49
	System	03 Oct 2020 20:27:49

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-03T13:27:30', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'f3c2045e-82c9-4f3c-8260-0bb09e78fb2c' User entered 'No (N)'	System	03 Oct 2020 20:27:49
	System	03 Oct 2020 20:27:49

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-03T13:27:35', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'f3c2045e-82c9-4f3c-8260-0bb09e78fb2c' User entered 'None (1)'	System	03 Oct 2020 20:27:49
	System	03 Oct 2020 20:27:49



**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-03T13:27:47', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'f3c2045e-82c9-4f3c-8260-0bb09e78fb2c' User entered '03 Oct 2020 13:27'	System	03 Oct 2020 20:27:49
	System	03 Oct 2020 20:27:49

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 5'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-04T21:56:31', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'b44a8823-50b4-4e83-806e-5c38d299029b'	System	05 Oct 2020 04:57:01
User entered 'None (1)'	System	05 Oct 2020 04:57:01

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-04T21:56:36', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'b44a8823-50b4-4e83-806e-5c38d299029b' User entered 'No (N)'	System	05 Oct 2020 04:57:01
	System	05 Oct 2020 04:57:01

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-04T21:56:42', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'b44a8823-50b4-4e83-806e-5c38d299029b' User entered 'No (N)'	System	05 Oct 2020 04:57:01
	System	05 Oct 2020 04:57:01

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-04T21:56:48', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'b44a8823-50b4-4e83-806e-5c38d299029b'	System	05 Oct 2020 04:57:01
User entered 'None (1)'	System	05 Oct 2020 04:57:01



US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-04T21:56:57', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'b44a8823-50b4-4e83-806e-5c38d299029b' User entered '04 Oct 2020 21:56'	System	05 Oct 2020 04:57:01
	System	05 Oct 2020 04:57:01

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 6'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-05T12:04:32', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c475dbb6-9cce-4819-9096-ce243d00757a' User entered 'None (1)'	System	05 Oct 2020 19:05:08
	System	05 Oct 2020 19:05:08

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-05T12:04:52', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c475dbb6-9cce-4819-9096-ce243d00757a' User entered 'No (N)'	System	05 Oct 2020 19:05:08
	System	05 Oct 2020 19:05:08

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-05T12:04:56', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c475dbb6-9cce-4819-9096-ce243d00757a' User entered 'No (N)'	System	05 Oct 2020 19:05:08
	System	05 Oct 2020 19:05:08

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-05T12:05:01', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c475dbb6-9cce-4819-9096-ce243d00757a' User entered 'None (1)'	System	05 Oct 2020 19:05:08
	System	05 Oct 2020 19:05:08



**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-05T12:05:05', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c475dbb6-9cce-4819-9096-ce243d00757a' User entered '05 Oct 2020 12:05'	System	05 Oct 2020 19:05:08
	System	05 Oct 2020 19:05:08

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 7'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-06T12:26:47', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '654bfb81-0afc-494a-a6d5-506c0082e433'	System	06 Oct 2020 19:27:08
User entered 'None (1)'	System	06 Oct 2020 19:27:08

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-06T12:26:51', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '654bfb81-0afc-494a-a6d5-506c0082e433' User entered 'No (N)'	System	06 Oct 2020 19:27:08
	System	06 Oct 2020 19:27:08

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-06T12:26:56', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '654bfb81-0afc-494a-a6d5-506c0082e433' User entered 'No (N)'	System	06 Oct 2020 19:27:08
	System	06 Oct 2020 19:27:08

US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:13

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-06T12:27:02', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '654bfb81-0afc-494a-a6d5-506c0082e433'	System	06 Oct 2020 19:27:08
User entered 'None (1)'	System	06 Oct 2020 19:27:08



US3642076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-06T12:27:06', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '654bfb81-0afc-494a-a6d5-506c0082e433' User entered '06 Oct 2020 12:27'	System	06 Oct 2020 19:27:08
	System	06 Oct 2020 19:27:08

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T14:59:23', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'd9ac8318-2adb-401b-931e-0f967e756a21' User entered 'None (0)'	System	30 Sep 2020 21:59:58
	System	30 Sep 2020 21:59:58

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T14:59:27', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'd9ac8318-2adb-401b-931e-0f967e756a21' User entered 'None (0)'	System	30 Sep 2020 21:59:58
	System	30 Sep 2020 21:59:58

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T14:59:30', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'd9ac8318-2adb-401b-931e-0f967e756a21' User entered 'None (0)'	System	30 Sep 2020 21:59:58
	System	30 Sep 2020 21:59:58

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T14:59:34', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'd9ac8318-2adb-401b-931e-0f967e756a21' User entered 'None (0)'	System	30 Sep 2020 21:59:58
	System	30 Sep 2020 21:59:58



**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T14:59:37', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'd9ac8318-2adb-401b-931e-0f967e756a21' User entered 'None (0)'	System	30 Sep 2020 21:59:58
	System	30 Sep 2020 21:59:58

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T14:59:40', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'd9ac8318-2adb-401b-931e-0f967e756a21' User entered 'None (0)'	System	30 Sep 2020 21:59:58
	System	30 Sep 2020 21:59:58

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:13

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)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T14:59:46', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'd9ac8318-2adb-401b-931e-0f967e756a21' User entered 'No (N)'	System	30 Sep 2020 21:59:58
	System	30 Sep 2020 21:59:58

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T14:59:56', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'd9ac8318-2adb-401b-931e-0f967e756a21' User entered '30 Sep 2020 14:59'	System	30 Sep 2020 21:59:58
	System	30 Sep 2020 21:59:58

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '30 Sep 2020 14:55'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '30 Sep 2020 17:25'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T20:35:40', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '24840b6c-ece9-424c-a5da-7f847afa3c91' User entered 'None (0)'	System	01 Oct 2020 03:36:16
	System	01 Oct 2020 03:36:16



**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T20:35:43', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '24840b6c-ece9-424c-a5da-7f847afa3c91' User entered 'None (0)'	System	01 Oct 2020 03:36:16
	System	01 Oct 2020 03:36:16

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T20:35:47', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '24840b6c-ece9-424c-a5da-7f847afa3c91' User entered 'None (0)'	System	01 Oct 2020 03:36:16
	System	01 Oct 2020 03:36:16

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T20:35:50', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '24840b6c-ece9-424c-a5da-7f847afa3c91' User entered 'None (0)'	System	01 Oct 2020 03:36:16
	System	01 Oct 2020 03:36:16

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T20:35:53', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '24840b6c-ece9-424c-a5da-7f847afa3c91' User entered 'None (0)'	System	01 Oct 2020 03:36:16
	System	01 Oct 2020 03:36:16

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T20:35:59', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '24840b6c-ece9-424c-a5da-7f847afa3c91' User entered 'None (0)'	System	01 Oct 2020 03:36:16
	System	01 Oct 2020 03:36:16

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:13

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)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T20:36:06', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '24840b6c-ece9-424c-a5da-7f847afa3c91' User entered 'No (N)'	System	01 Oct 2020 03:36:16
	System	01 Oct 2020 03:36:16

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-09-30T20:36:14', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '24840b6c-ece9-424c-a5da-7f847afa3c91'	System	01 Oct 2020 03:36:16
User entered '30 Sep 2020 20:36'	System	01 Oct 2020 03:36:16

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '30 Sep 2020 18:20'	System	30 Sep 2020 21:42:36



**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 2'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-01T16:06:24', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '9e3f3379-e533-4395-b3d4-96e7b4c9a809' User entered 'None (0)'	System	01 Oct 2020 23:07:03
	System	01 Oct 2020 23:07:03

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-01T16:06:28', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '9e3f3379-e533-4395-b3d4-96e7b4c9a809' User entered 'None (0)'	System	01 Oct 2020 23:07:03
	System	01 Oct 2020 23:07:03

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-01T16:06:32', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '9e3f3379-e533-4395-b3d4-96e7b4c9a809' User entered 'None (0)'	System	01 Oct 2020 23:07:03
	System	01 Oct 2020 23:07:03

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-01T16:06:39', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '9e3f3379-e533-4395-b3d4-96e7b4c9a809' User entered 'None (0)'	System	01 Oct 2020 23:07:03
	System	01 Oct 2020 23:07:03

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-01T16:06:42', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '9e3f3379-e533-4395-b3d4-96e7b4c9a809' User entered 'None (0)'	System	01 Oct 2020 23:07:03
	System	01 Oct 2020 23:07:03

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-01T16:06:46', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '9e3f3379-e533-4395-b3d4-96e7b4c9a809' User entered 'None (0)'	System	01 Oct 2020 23:07:03
	System	01 Oct 2020 23:07:03



US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:13

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)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-01T16:06:52', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '9e3f3379-e533-4395-b3d4-96e7b4c9a809' User entered 'No (N)'	System	01 Oct 2020 23:07:03
	System	01 Oct 2020 23:07:03

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-01T16:07:00', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '9e3f3379-e533-4395-b3d4-96e7b4c9a809' User entered '01 Oct 2020 16:07'	System	01 Oct 2020 23:07:03
	System	01 Oct 2020 23:07:03

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 3'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-02T12:08:26', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '7ada148e-66e6-4041-9d28-e4703b50ccdd' User entered 'None (0)'	System	02 Oct 2020 19:08:56
	System	02 Oct 2020 19:08:56

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-02T12:08:30', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '7ada148e-66e6-4041-9d28-e4703b50ccdd' User entered 'None (0)'	System	02 Oct 2020 19:08:56
	System	02 Oct 2020 19:08:56

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-02T12:08:32', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '7ada148e-66e6-4041-9d28-e4703b50ccdd' User entered 'None (0)'	System	02 Oct 2020 19:08:56
	System	02 Oct 2020 19:08:56



US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-02T12:08:36', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '7ada148e-66e6-4041-9d28-e4703b50ccdd' User entered 'None (0)'	System	02 Oct 2020 19:08:56
	System	02 Oct 2020 19:08:56

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-02T12:08:39', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '7ada148e-66e6-4041-9d28-e4703b50ccdd' User entered 'None (0)'	System	02 Oct 2020 19:08:56
	System	02 Oct 2020 19:08:56

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-02T12:08:42', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '7ada148e-66e6-4041-9d28-e4703b50ccdd' User entered 'None (0)'	System	02 Oct 2020 19:08:56
	System	02 Oct 2020 19:08:56

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:13

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)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-02T12:08:47', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '7ada148e-66e6-4041-9d28-e4703b50ccdd' User entered 'No (N)'	System	02 Oct 2020 19:08:56
	System	02 Oct 2020 19:08:56

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-02T12:08:54', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '7ada148e-66e6-4041-9d28-e4703b50ccdd' User entered '02 Oct 2020 12:08'	System	02 Oct 2020 19:08:56
	System	02 Oct 2020 19:08:56

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 4'	System	30 Sep 2020 21:42:36



US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-03T13:27:55', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '4f64a4e0-1071-43c7-8ccd-607b58bf66af' User entered 'None (0)'	System	03 Oct 2020 20:28:33
	System	03 Oct 2020 20:28:33

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:13

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-03T13:28:00', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '4f64a4e0-1071-43c7-8ccd-607b58bf66af' User entered 'None (0)'	System	03 Oct 2020 20:28:33
	System	03 Oct 2020 20:28:33

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-03T13:28:03', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '4f64a4e0-1071-43c7-8ccd-607b58bf66af' User entered 'None (0)'	System	03 Oct 2020 20:28:33
	System	03 Oct 2020 20:28:33

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:13**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-03T13:28:06', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '4f64a4e0-1071-43c7-8ccd-607b58bf66af' User entered 'None (0)'	System	03 Oct 2020 20:28:33
	System	03 Oct 2020 20:28:33

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-03T13:28:09', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '4f64a4e0-1071-43c7-8ccd-607b58bf66af' User entered 'None (0)'	System	03 Oct 2020 20:28:33
	System	03 Oct 2020 20:28:33

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-03T13:28:14', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '4f64a4e0-1071-43c7-8ccd-607b58bf66af' User entered 'None (0)'	System	03 Oct 2020 20:28:33
	System	03 Oct 2020 20:28:33

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:13

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)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-03T13:28:25', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '4f64a4e0-1071-43c7-8ccd-607b58bf66af' User entered 'No (N)'	System	03 Oct 2020 20:28:33
	System	03 Oct 2020 20:28:33

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-03T13:28:28', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '4f64a4e0-1071-43c7-8ccd-607b58bf66af' User entered '03 Oct 2020 13:28'	System	03 Oct 2020 20:28:33
	System	03 Oct 2020 20:28:33



**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 5'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-04T21:57:06', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '05e8821e-aba1-441b-8522-6cc01fd04af5' User entered 'None (0)'	System	05 Oct 2020 04:58:00
	System	05 Oct 2020 04:58:00

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-04T21:57:10', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '05e8821e-aba1-441b-8522-6cc01fd04af5' User entered 'None (0)'	System	05 Oct 2020 04:58:00
	System	05 Oct 2020 04:58:00

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-04T21:57:14', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '05e8821e-aba1-441b-8522-6cc01fd04af5' User entered 'None (0)'	System	05 Oct 2020 04:58:00
	System	05 Oct 2020 04:58:00

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:13

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-04T21:57:19', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '05e8821e-aba1-441b-8522-6cc01fd04af5' User entered 'None (0)'	System	05 Oct 2020 04:58:00
	System	05 Oct 2020 04:58:00

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:13

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-04T21:57:26', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '05e8821e-aba1-441b-8522-6cc01fd04af5' User entered 'None (0)'	System	05 Oct 2020 04:58:00
	System	05 Oct 2020 04:58:00



**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-04T21:57:33', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '05e8821e-aba1-441b-8522-6cc01fd04af5' User entered 'None (0)'	System	05 Oct 2020 04:58:00
	System	05 Oct 2020 04:58:00

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:13

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)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-04T21:57:38', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '05e8821e-aba1-441b-8522-6cc01fd04af5' User entered 'No (N)'	System	05 Oct 2020 04:58:00
	System	05 Oct 2020 04:58:00

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-04T21:57:55', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '05e8821e-aba1-441b-8522-6cc01fd04af5' User entered '04 Oct 2020 21:57'	System	05 Oct 2020 04:58:00
	System	05 Oct 2020 04:58:00

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:13

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 6'	System	30 Sep 2020 21:42:36

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:13

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-05T12:05:18', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'baabb763-6551-4614-9e17-aeb8b66f0afc' User entered 'None (0)'	System	05 Oct 2020 19:05:49
	System	05 Oct 2020 19:05:49

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-05T12:05:21', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'baabb763-6551-4614-9e17-aeb8b66f0afc' User entered 'None (0)'	System	05 Oct 2020 19:05:49
	System	05 Oct 2020 19:05:49



US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-05T12:05:25', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'baabb763-6551-4614-9e17-aeb8b66f0afc' User entered 'None (0)'	System	05 Oct 2020 19:05:49
	System	05 Oct 2020 19:05:49

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-05T12:05:30', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'baabb763-6551-4614-9e17-aeb8b66f0afc' User entered 'None (0)'	System	05 Oct 2020 19:05:49
	System	05 Oct 2020 19:05:49

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-05T12:05:35', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'baabb763-6551-4614-9e17-aeb8b66f0afc' User entered 'None (0)'	System	05 Oct 2020 19:05:49
	System	05 Oct 2020 19:05:49

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:13

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-05T12:05:38', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'baabb763-6551-4614-9e17-aeb8b66f0afc' User entered 'None (0)'	System	05 Oct 2020 19:05:49
	System	05 Oct 2020 19:05:49

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:13

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)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-05T12:05:42', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'baabb763-6551-4614-9e17-aeb8b66f0afc' User entered 'No (N)'	System	05 Oct 2020 19:05:49
	System	05 Oct 2020 19:05:49

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-05T12:05:46', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'baabb763-6551-4614-9e17-aeb8b66f0afc' User entered '05 Oct 2020 12:05'	System	05 Oct 2020 19:05:49
	System	05 Oct 2020 19:05:49

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 21:42:36



**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	30 Sep 2020 21:42:36
User entered 'Day 7'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-06T12:27:19', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '826e7e4e-9ec6-476e-a9fe-f1af192c1747' User entered 'None (0)'	System	06 Oct 2020 19:27:56
	System	06 Oct 2020 19:27:56

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-06T12:27:22', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '826e7e4e-9ec6-476e-a9fe-f1af192c1747' User entered 'None (0)'	System	06 Oct 2020 19:27:56
	System	06 Oct 2020 19:27:56

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:13

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-06T12:27:31', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '826e7e4e-9ec6-476e-a9fe-f1af192c1747' User entered 'None (0)'	System	06 Oct 2020 19:27:56
	System	06 Oct 2020 19:27:56

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-06T12:27:35', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '826e7e4e-9ec6-476e-a9fe-f1af192c1747' User entered 'None (0)'	System	06 Oct 2020 19:27:56
	System	06 Oct 2020 19:27:56

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-06T12:27:38', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '826e7e4e-9ec6-476e-a9fe-f1af192c1747' User entered 'None (0)'	System	06 Oct 2020 19:27:56
	System	06 Oct 2020 19:27:56

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-06T12:27:41', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '826e7e4e-9ec6-476e-a9fe-f1af192c1747' User entered 'None (0)'	System	06 Oct 2020 19:27:56
	System	06 Oct 2020 19:27:56

US3642076

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:13

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)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-06T12:27:48', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '826e7e4e-9ec6-476e-a9fe-f1af192c1747' User entered 'No (N)'	System	06 Oct 2020 19:27:56
	System	06 Oct 2020 19:27:56



**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-10-06T12:27:53', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '826e7e4e-9ec6-476e-a9fe-f1af192c1747' User entered '06 Oct 2020 12:27'	System	06 Oct 2020 19:27:56
	System	06 Oct 2020 19:27:56

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:13**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 21:42:36

**US3642076**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	07 Oct 2020 15:44:15

**US3642076**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '7 Oct 2020'	Colleen McLellan (b) (4)	07 Oct 2020 15:44:15

US3642076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Contact Made (CONTACT MADE)'	Colleen McLellan (b) (4)	07 Oct 2020 15:44:15

US3642076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Colleen McLellan (b) (4)	07 Oct 2020 15:44:15

US3642076

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	07 Oct 2020 15:44:19



**US3642076**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'I'	System	07 Oct 2020 15:44:19

**US3642076**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	16 Oct 2020 20:37:18

**US3642076**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '16 Oct 2020'	(b) (4) Lindsey Woronicz (b) (4)	16 Oct 2020 20:37:18

US3642076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lindsey Woronicz (b) (4)	16 Oct 2020 20:37:18

US3642076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	(b) (4) Lindsey Woronicz (b) (4)	16 Oct 2020 20:37:18

US3642076

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	16 Oct 2020 20:37:23

**US3642076**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'I'	System	16 Oct 2020 20:37:23

**US3642076**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	23 Oct 2020 17:33:07



**US3642076**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '23 Oct 2020'	Jennifer Morales (b) (4)	23 Oct 2020 17:33:07

**US3642076**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Contact Made (CONTACT MADE)'	Jennifer Morales (b) (4)	23 Oct 2020 17:33:07

**US3642076**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Jennifer Morales (b) (4)	23 Oct 2020 17:33:07

US3642076

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	23 Oct 2020 17:33:16

**US3642076**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'I'	System	23 Oct 2020 17:33:16

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	30 Oct 2020 15:15:02

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '28 Oct 2020'	Son Do (b) (4)	30 Oct 2020 15:15:02

US3642076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Clinic (Clinic)'	Son Do (b) (4)	30 Oct 2020 15:15:02



**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'VISIT3'	System	30 Oct 2020 15:15:02

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	30 Oct 2020 15:15:30

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '28 Oct 2020'	Son Do (b) (4)	30 Oct 2020 15:15:30

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '13:38'	Son Do (b) (4)	30 Oct 2020 15:15:30

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered '28 Oct 2020 13:38'	System	30 Oct 2020 15:15:30

US3642076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '97' F	Son Do (b) (4)	30 Oct 2020 15:15:30

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Oral (Oral)'	Son Do (b) (4)	30 Oct 2020 15:15:30

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Son Do (b) (4)	30 Oct 2020 15:15:30



**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '104'	Son Do (b) (4)	30 Oct 2020 15:15:30

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'bpm'	System	30 Oct 2020 15:15:30

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '20'	Son Do (b) (4)	30 Oct 2020 15:15:30

US3642076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'breaths/min'	System	30 Oct 2020 15:15:30

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '142'	Son Do (b) (4)	30 Oct 2020 15:15:30

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'mmHg'	System	30 Oct 2020 15:15:30

US3642076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '90'	Son Do (b) (4)	30 Oct 2020 15:15:30

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'mmHg'	System	30 Oct 2020 15:15:30



**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:13**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	30 Oct 2020 15:15:43

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:13**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '28 Oct 2020'	Son Do (b) (4)	30 Oct 2020 15:15:43

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	30 Oct 2020 15:15:54

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:13**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '28 Oct 2020'	Son Do (b) (4)	30 Oct 2020 15:15:54

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:13**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '14:05'	Son Do (b) (4)	30 Oct 2020 15:15:54

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered '28 Oct 2020 14:05'	System	30 Oct 2020 15:15:54



**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Son Do (b) (4)	30 Oct 2020 15:15:58

**US3642076**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'I'	System	30 Oct 2020 15:15:58

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 64'	System	02 Sep 2020 00:37:55

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-11-01T10:17:05', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '40bbe56a-1fef-415b-9861-2b9beae3730d' User entered 'No (N)'	System	01 Nov 2020 18:17:21
	System	01 Nov 2020 18:17:21

US3642076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-11-01T10:17:11', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '40bbe56a-1fef-415b-9861-2b9beae3730d' User entered 'No (N)'	System	01 Nov 2020 18:17:21
	System	01 Nov 2020 18:17:21

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-11-01T10:17:19', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '40bbe56a-1fef-415b-9861-2b9beae3730d' User entered '01 Nov 2020 10:17:19'	System	01 Nov 2020 18:17:21
	System	01 Nov 2020 18:17:21

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered '01 Nov 2020 00:01'	System	02 Sep 2020 00:37:55

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered '05 Nov 2020 23:59'	System	02 Sep 2020 00:37:55



**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 71'	System	02 Sep 2020 00:37:55

US3642076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-11-08T00:07:57', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '0c2ce7d0-4bed-481f-b0cd-3fd2125d1583' User entered 'No (N)'	System	08 Nov 2020 08:08:36
	System	08 Nov 2020 08:08:36

US3642076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-11-08T00:08:12', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '0c2ce7d0-4bed-481f-b0cd-3fd2125d1583'	System	08 Nov 2020 08:08:36
User entered 'No (N)'	System	08 Nov 2020 08:08:36

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-11-08T00:08:30', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '0c2ce7d0-4bed-481f-b0cd-3fd2125d1583' User entered '08 Nov 2020 00:08:30'	System	08 Nov 2020 08:08:36
	System	08 Nov 2020 08:08:36

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered '08 Nov 2020 00:01'	System	02 Sep 2020 00:37:55

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered '12 Nov 2020 23:59'	System	02 Sep 2020 00:37:55

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered 'Day 78'	System	02 Sep 2020 00:37:55

US3642076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-11-15T00:50:11', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '616a4715-302d-493b-ae06-0855ac7e4bff'	System	15 Nov 2020 08:50:27
User entered 'No (N)'	System	15 Nov 2020 08:50:27



US3642076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-11-15T00:50:19', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '616a4715-302d-493b-ae06-0855ac7e4bff'	System	15 Nov 2020 08:50:27
User entered 'No (N)'	System	15 Nov 2020 08:50:27

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-11-15T00:50:24', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '616a4715-302d-493b-ae06-0855ac7e4bff' User entered '15 Nov 2020 00:50:24'	System	15 Nov 2020 08:50:27
	System	15 Nov 2020 08:50:27

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered '15 Nov 2020 00:01'	System	02 Sep 2020 00:37:55

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:24
Data entry locked.	System	02 Sep 2020 00:37:55
User entered '19 Nov 2020 23:59'	System	02 Sep 2020 00:37:55

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 22:07:45



**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-11-29T09:19:37', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '035dcff8-62ec-4059-9594-d141b2c1c8c9' User entered 'No (N)'	System	29 Nov 2020 17:19:55
	System	29 Nov 2020 17:19:55

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-11-29T09:19:42', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '035dcff8-62ec-4059-9594-d141b2c1c8c9' User entered 'No (N)'	System	29 Nov 2020 17:19:55
	System	29 Nov 2020 17:19:55

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-11-29T09:19:52', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '035dcff8-62ec-4059-9594-d141b2c1c8c9' User entered '29 Nov 2020 09:19:52'	System	29 Nov 2020 17:19:55
	System	29 Nov 2020 17:19:55

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-12-06T06:23:31', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '31a8c965-f243-40e6-b6cc-a9a7959c930e' User entered 'No (N)'	System	06 Dec 2020 14:23:52
	System	06 Dec 2020 14:23:52

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-12-06T06:23:40', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '31a8c965-f243-40e6-b6cc-a9a7959c930e' User entered 'No (N)'	System	06 Dec 2020 14:23:52



**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-12-06T06:23:49', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '31a8c965-f243-40e6-b6cc-a9a7959c930e' User entered '06 Dec 2020 06:23:49'	System	06 Dec 2020 14:23:52
	System	06 Dec 2020 14:23:52

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-12-12T13:01:25', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '5da6251c-0f99-47b3-b779-d381da7a4711' User entered 'No (N)'	System	12 Dec 2020 21:01:42
	System	12 Dec 2020 21:01:42

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-12-12T13:01:33', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '5da6251c-0f99-47b3-b779-d381da7a4711' User entered 'No (N)'	System	12 Dec 2020 21:01:42
	System	12 Dec 2020 21:01:42

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-12-12T13:01:37', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '5da6251c-0f99-47b3-b779-d381da7a4711' User entered '12 Dec 2020 13:01:37'	System	12 Dec 2020 21:01:42
	System	12 Dec 2020 21:01:42

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 22:07:45



**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-12-17T00:01:25', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'b02775e4-c5b6-4b52-baae-cef88d0d86c0' User entered 'No (N)'	System	17 Dec 2020 08:01:56
	System	17 Dec 2020 08:01:56

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-12-17T00:01:42', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'b02775e4-c5b6-4b52-baae-cef88d0d86c0'	System	17 Dec 2020 08:01:56
User entered 'No (N)'	System	17 Dec 2020 08:01:56

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-12-17T00:01:52', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'b02775e4-c5b6-4b52-baae-cef88d0d86c0' User entered '17 Dec 2020 00:01:52'	System	17 Dec 2020 08:01:56
	System	17 Dec 2020 08:01:56

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:07:45



**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-12-24T00:01:33', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '3dde4673-6625-4550-ac24-b59f5f3244d8' User entered 'No (N)'	System	24 Dec 2020 08:01:50
	System	24 Dec 2020 08:01:50

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-12-24T00:01:41', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '3dde4673-6625-4550-ac24-b59f5f3244d8'	System	24 Dec 2020 08:01:50
User entered 'No (N)'	System	24 Dec 2020 08:01:50

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-12-24T00:01:46', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '3dde4673-6625-4550-ac24-b59f5f3244d8' User entered '24 Dec 2020 00:01:46'	System	24 Dec 2020 08:01:50
	System	24 Dec 2020 08:01:50

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-12-31T09:50:28', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8211b2f7-119b-4213-9570-eac165a7b206' User entered 'No (N)'	System	31 Dec 2020 17:50:43
	System	31 Dec 2020 17:50:43

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-12-31T09:50:34', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8211b2f7-119b-4213-9570-eac165a7b206'	System	31 Dec 2020 17:50:43
User entered 'No (N)'	System	31 Dec 2020 17:50:43



**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2020-12-31T09:50:40', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8211b2f7-119b-4213-9570-eac165a7b206' User entered '31 Dec 2020 09:50:40'	System	31 Dec 2020 17:50:43
	System	31 Dec 2020 17:50:43

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-01-07T11:25:19', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '5d0831dd-c8b9-4818-8922-5dc475e57a50'	System	07 Jan 2021 19:25:33
User entered 'No (N)'	System	07 Jan 2021 19:25:33

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-01-07T11:25:23', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '5d0831dd-c8b9-4818-8922-5dc475e57a50'	System	07 Jan 2021 19:25:33
User entered 'No (N)'	System	07 Jan 2021 19:25:33

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-01-07T11:25:29', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '5d0831dd-c8b9-4818-8922-5dc475e57a50'	System	07 Jan 2021 19:25:33
User entered '07 Jan 2021 11:25:29'	System	07 Jan 2021 19:25:33

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 22:07:45



**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-01-14T12:40:03', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'a527d000-f079-4687-b50a-652a9e3e6ce9' User entered 'No (N)'	System	14 Jan 2021 20:40:16
	System	14 Jan 2021 20:40:16

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-01-14T12:40:08', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'a527d000-f079-4687-b50a-652a9e3e6ce9' User entered 'No (N)'	System	14 Jan 2021 20:40:16
	System	14 Jan 2021 20:40:16

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-01-14T12:40:14', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'a527d000-f079-4687-b50a-652a9e3e6ce9' User entered '14 Jan 2021 12:40:14'	System	14 Jan 2021 20:40:16
	System	14 Jan 2021 20:40:16

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-01-21T07:33:52', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8c5796ea-3edf-4c70-a3d9-5b77d095b50d' User entered 'No (N)'	System	21 Jan 2021 15:34:15
	System	21 Jan 2021 15:34:15

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-01-21T07:34:01', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8c5796ea-3edf-4c70-a3d9-5b77d095b50d' User entered 'No (N)'	System	21 Jan 2021 15:34:15

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-01-21T07:34:10', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '8c5796ea-3edf-4c70-a3d9-5b77d095b50d' User entered '21 Jan 2021 07:34:10'	System	21 Jan 2021 15:34:15
	System	21 Jan 2021 15:34:15

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-01-28T08:50:55', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c4630b0c-5274-4559-9756-8c11207283fa' User entered 'No (N)'	System	28 Jan 2021 16:51:16
	System	28 Jan 2021 16:51:16

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-01-28T08:51:06', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c4630b0c-5274-4559-9756-8c11207283fa' User entered 'No (N)'	System	28 Jan 2021 16:51:16
	System	28 Jan 2021 16:51:16



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-01-28T08:51:12', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c4630b0c-5274-4559-9756-8c11207283fa' User entered '28 Jan 2021 08:51:12'	System	28 Jan 2021 16:51:16
	System	28 Jan 2021 16:51:16

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-02-04T05:23:48', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '04c82eec-137e-423a-a10c-3819420a34c8' User entered 'Yes (Y)'	System	04 Feb 2021 13:24:27
	System	04 Feb 2021 13:24:27

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-02-04T05:23:55', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '04c82eec-137e-423a-a10c-3819420a34c8' User entered 'No (N)'	System	04 Feb 2021 13:24:27
	System	04 Feb 2021 13:24:27

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-02-04T05:24:05', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '04c82eec-137e-423a-a10c-3819420a34c8' User entered 'No (N)'	System	04 Feb 2021 13:24:27
	System	04 Feb 2021 13:24:27

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-02-04T05:24:12', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '04c82eec-137e-423a-a10c-3819420a34c8' User entered 'No (N)'	System	04 Feb 2021 13:24:27
	System	04 Feb 2021 13:24:27



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-02-04T05:24:24', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '04c82eec-137e-423a-a10c-3819420a34c8' User entered '04 Feb 2021 05:24:24'	System	04 Feb 2021 13:24:27
	System	04 Feb 2021 13:24:27

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-02-11T09:00:46', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'e3c00324-a615-4170-9437-9ca30aa8b506'	System	11 Feb 2021 17:04:47
User entered 'Yes (Y)'	System	11 Feb 2021 17:04:47

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-02-11T09:00:49', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'e3c00324-a615-4170-9437-9ca30aa8b506'	System	11 Feb 2021 17:04:47
User entered 'No (N)'	System	11 Feb 2021 17:04:47

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-02-11T09:00:55', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'e3c00324-a615-4170-9437-9ca30aa8b506' User entered 'No (N)'	System	11 Feb 2021 17:04:47
	System	11 Feb 2021 17:04:47

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-02-11T09:01:03', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'e3c00324-a615-4170-9437-9ca30aa8b506' User entered 'No (N)'	System	11 Feb 2021 17:04:47
	System	11 Feb 2021 17:04:47



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-02-11T09:01:07', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'e3c00324-a615-4170-9437-9ca30aa8b506'	System	11 Feb 2021 17:04:47
User entered '11 Feb 2021 09:01:07'	System	11 Feb 2021 17:04:47

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-02-18T12:27:17', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'a9ab7578-9f0b-4bbd-beff-44fc114d0a21'	System	18 Feb 2021 20:27:46
User entered 'No (N)'	System	18 Feb 2021 20:27:46

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-02-18T12:27:23', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'a9ab7578-9f0b-4bbd-beff-44fc114d0a21' User entered 'No (N)'	System	18 Feb 2021 20:27:46

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-02-18T12:27:43', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'a9ab7578-9f0b-4bbd-beff-44fc114d0a21' User entered '18 Feb 2021 12:27:43'	System	18 Feb 2021 20:27:46
	System	18 Feb 2021 20:27:46

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-02-25T08:46:11', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '97de7c50-8bb6-46a0-bd5d-39ac0041dbdb' User entered 'Yes (Y)'	System	25 Feb 2021 16:47:07
	System	25 Feb 2021 16:47:07

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-02-25T08:46:19', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '97de7c50-8bb6-46a0-bd5d-39ac0041dbdb' User entered 'No (N)'	System	25 Feb 2021 16:47:07

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-02-25T08:46:26', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '97de7c50-8bb6-46a0-bd5d-39ac0041dbdb' User entered 'No (N)'	System	25 Feb 2021 16:47:07
	System	25 Feb 2021 16:47:07

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-02-25T08:46:34', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '97de7c50-8bb6-46a0-bd5d-39ac0041dbdb' User entered 'Yes (Y)'	System	25 Feb 2021 16:47:07
	System	25 Feb 2021 16:47:07

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Please 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-02-25T08:46:50', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '97de7c50-8bb6-46a0-bd5d-39ac0041dbdb'	System	25 Feb 2021 16:47:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Feb 2021 16:47:07

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-02-25T08:46:55', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '97de7c50-8bb6-46a0-bd5d-39ac0041dbdb' User entered '25 Feb 2021 08:46:55'	System	25 Feb 2021 16:47:07



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-03-04T00:01:52', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '7cecc29d-2e5a-4e95-bb20-2618bfdf1d33'	System	04 Mar 2021 08:02:20
User entered 'Yes (Y)'	System	04 Mar 2021 08:02:20

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-03-04T00:01:59', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '7cecc29d-2e5a-4e95-bb20-2618bfdf1d33'	System	04 Mar 2021 08:02:20
User entered 'No (N)'	System	04 Mar 2021 08:02:20

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-03-04T00:02:06', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '7cecc29d-2e5a-4e95-bb20-2618bfdf1d33'	System	04 Mar 2021 08:02:20
User entered 'No (N)'	System	04 Mar 2021 08:02:20

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-03-04T00:02:13', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '7cecc29d-2e5a-4e95-bb20-2618bfdf1d33'	System	04 Mar 2021 08:02:20
User entered 'No (N)'	System	04 Mar 2021 08:02:20

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-03-04T00:02:18', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '7cecc29d-2e5a-4e95-bb20-2618bdfd1d33'	System	04 Mar 2021 08:02:20
User entered '04 Mar 2021 00:02:18'	System	04 Mar 2021 08:02:20



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-03-11T03:47:19', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1e3f019e-0479-486b-9955-c457886a2a68'	System	11 Mar 2021 11:47:40
User entered 'No (N)'	System	11 Mar 2021 11:47:40

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-03-11T03:47:25', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1e3f019e-0479-486b-9955-c457886a2a68'	System	11 Mar 2021 11:47:40
User entered 'No (N)'	System	11 Mar 2021 11:47:40

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-03-11T03:47:35', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '1e3f019e-0479-486b-9955-c457886a2a68' User entered '11 Mar 2021 03:47:35'	System	11 Mar 2021 11:47:40
	System	11 Mar 2021 11:47:40

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-03-18T02:48:02', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'ba6e6278-1bca-46b8-88d3-78a5512a3149'	System	18 Mar 2021 09:48:51
User entered 'No (N)'	System	18 Mar 2021 09:48:51

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-03-18T02:48:39', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'ba6e6278-1bca-46b8-88d3-78a5512a3149'	System	18 Mar 2021 09:48:51
User entered 'No (N)'	System	18 Mar 2021 09:48:51

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-03-18T02:48:48', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'ba6e6278-1bca-46b8-88d3-78a5512a3149' User entered '18 Mar 2021 02:48:48'	System	18 Mar 2021 09:48:51
	System	18 Mar 2021 09:48:51

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-03-25T06:40:39', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '5d9ba69d-be54-4c16-8095-147836b68b1f' User entered 'No (N)'	System	25 Mar 2021 13:41:04
	System	25 Mar 2021 13:41:04



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-03-25T06:40:51', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '5d9ba69d-be54-4c16-8095-147836b68b1f' User entered 'No (N)'	System	25 Mar 2021 13:41:04

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-03-25T06:40:58', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '5d9ba69d-be54-4c16-8095-147836b68b1f' User entered '25 Mar 2021 06:40:58'	System	25 Mar 2021 13:41:04

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-04-01T00:02:02', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c0b78fc6-4146-4917-95d9-90f76d89ec50' User entered 'No (N)'	System	01 Apr 2021 07:02:18
	System	01 Apr 2021 07:02:18

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-04-01T00:02:09', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c0b78fc6-4146-4917-95d9-90f76d89ec50'	System	01 Apr 2021 07:02:18
User entered 'No (N)'	System	01 Apr 2021 07:02:18

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-04-01T00:02:13', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'c0b78fc6-4146-4917-95d9-90f76d89ec50'	System	01 Apr 2021 07:02:18
User entered '01 Apr 2021 00:02:13'	System	01 Apr 2021 07:02:18



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-04-10T12:01:40', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '6e043a27-5846-4bfe-91bf-c22f97b3a62b' User entered 'No (N)'	System	10 Apr 2021 19:02:16
	System	10 Apr 2021 19:02:16

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-04-10T12:01:46', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '6e043a27-5846-4bfe-91bf-c22f97b3a62b' User entered 'No (N)'	System	10 Apr 2021 19:02:16

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-04-10T12:01:52', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '6e043a27-5846-4bfe-91bf-c22f97b3a62b' User entered '10 Apr 2021 12:01:52'	System	10 Apr 2021 19:02:16
	System	10 Apr 2021 19:02:16

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-04-15T00:03:25', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '3e2979f1-8669-42dc-ae8-89175b42f800'	System	15 Apr 2021 07:04:15
User entered 'No (N)'	System	15 Apr 2021 07:04:15

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-04-15T00:03:35', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '3e2979f1-8669-42dc-ae8-89175b42f800'	System	15 Apr 2021 07:04:15
User entered 'No (N)'	System	15 Apr 2021 07:04:15

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-04-15T00:03:39', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '3e2979f1-8669-42dc-ae8-89175b42f800' User entered '15 Apr 2021 00:03:39'	System	15 Apr 2021 07:04:15
	System	15 Apr 2021 07:04:15

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-04-22T06:55:59', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '131e1a77-1739-437d-95e5-9b8e0e9a88ae' User entered 'No (N)'	System	22 Apr 2021 13:56:11
	System	22 Apr 2021 13:56:11



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-04-22T06:56:04', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '131e1a77-1739-437d-95e5-9b8e0e9a88ae' User entered 'No (N)'	System	22 Apr 2021 13:56:11

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-04-22T06:56:07', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '131e1a77-1739-437d-95e5-9b8e0e9a88ae' User entered '22 Apr 2021 06:56:07'	System	22 Apr 2021 13:56:11
	System	22 Apr 2021 13:56:11

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-04-29T00:01:30', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'ff3cf426-be3c-4ac3-808e-0b448d32dc50'	System	29 Apr 2021 07:01:43
User entered 'No (N)'	System	29 Apr 2021 07:01:43

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Have you been exposed to someone with 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 (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-04-29T00:01:36', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'ff3cf426-be3c-4ac3-808e-0b448d32dc50'	System	29 Apr 2021 07:01:43
User entered 'No (N)'	System	29 Apr 2021 07:01:43

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-04-29T00:01:40', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: 'ff3cf426-be3c-4ac3-808e-0b448d32dc50' User entered '29 Apr 2021 00:01:40'	System	29 Apr 2021 07:01:43
	System	29 Apr 2021 07:01:43



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 22:07:45



**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 22:07:45

**US3642076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:13**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:07:45
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 22:07:45

US3642076

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:13:13

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)	30 Apr 2021 19:02:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-03-04T00:02:31', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '93d970fb-f67d-4a0b-9c6b-2b5b96735650'	System	04 Mar 2021 08:02:44
User entered 'No (N)'	System	04 Mar 2021 08:02:44



**US3642076**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8AC65541-CF73-4567-9C7D-585D602BDBBA)', Time: '2021-03-04T00:02:40', User OID: 'PatientReportedOutcome (US3642076)', ODM File OID: '93d970fb-f67d-4a0b-9c6b-2b5b96735650' User entered '04 Mar 2021 00:02:40'	System	04 Mar 2021 08:02:44
	System	04 Mar 2021 08:02:44

**US3642076**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	25 Nov 2020 17:20:45

**US3642076**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '25 Nov 2020'	Jennifer Morales (b) (4)	25 Nov 2020 17:20:45

**US3642076**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Contact Made (CONTACT MADE)'	Jennifer Morales (b) (4)	25 Nov 2020 17:20:45

**US3642076**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	Jennifer Morales (b) (4)	25 Nov 2020 17:20:45

**US3642076**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	25 Nov 2020 17:20:51

**US3642076**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:17:42
User entered 'I'	System	25 Nov 2020 17:20:51

**US3642076**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4)	13 Jan 2021 01:41:21



**US3642076**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '12 Jan 2021'	(b) (4) Jennifer Morales (b) (4)	13 Jan 2021 01:41:21

**US3642076**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Morales (b) (4)	13 Jan 2021 01:41:21

**US3642076**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	Jennifer Morales (b) (4)	13 Jan 2021 01:41:21

**US3642076**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4)	13 Jan 2021 01:41:27

**US3642076**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:04
User entered 'I'	System	13 Jan 2021 01:41:27

**US3642076**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Lindsey Woronicz (b) (4)	01 Feb 2021 23:59:33
User entered 'No (N)'	(b) (4)	
	Lindsey Woronicz (b) (4)	01 Feb 2021 23:42:55

**US3642076**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '29 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Lindsey Woronicz (b) (4)	01 Feb 2021 23:59:33
User entered empty.	Lindsey Woronicz (b) (4)	01 Feb 2021 23:42:55

US3642076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Lindsey Woronicz (b) (4)	01 Feb 2021 23:59:33
User entered empty.	Lindsey Woronicz (b) (4)	01 Feb 2021 23:42:55



**US3642076**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	(b) (4) Lindsey Woronicz (b) (4)	01 Feb 2021 23:42:55

US3642076

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:04
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	01 Feb 2021 23:42:59

**US3642076**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:04
User entered 'I'	System	01 Feb 2021 23:42:59

**US3642076**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:04
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered 'Yes (Y)'	(b) (4) Jennifer Morales (b) (4)	09 Mar 2021 20:38:48

US3642076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:04
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 10:17:47
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'CONTACT MADE OUT OF TREATMENT WINDOW' (Site from System).	Jennifer Morales (b) (4) (b) (4)	09 Mar 2021 20:39:05
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Mar 2021 20:38:48
User entered '09 Mar 2021'	Jennifer Morales (b) (4) (b) (4)	09 Mar 2021 20:38:48

**US3642076**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:04
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered 'Contact Made (CONTACT MADE)'	Jennifer Morales (b) (4)	09 Mar 2021 20:38:48

US3642076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:13

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:04
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered 'ATTEMPT 1 03MAR2021 Voicemail Not Set Up	(b) (4) Jennifer Morales (b) (4)	09 Mar 2021 20:39:28
ATTEMPT 2 03MAR2021 1755P		
ATTEMPT 3 08MAR2021 0940A EMAIL SENT'		
reason for change: Data Entry Error		
User entered empty.	Jennifer Morales (b) (4)	09 Mar 2021 20:38:48
	(b) (4)	

**US3642076**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:04
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	09 Mar 2021 16:30:12



**US3642076**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:19:04
User entered 'I'	System	09 Mar 2021 16:30:12

US3642076

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:13:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 16:37:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 16:37:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Megan Loughran (b) (4)	05 Apr 2021 16:37:11
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 16:33:47
User entered empty; reason for change Data Entry Error	Megan Loughran (b) (4)	05 Apr 2021 16:33:47
	(b) (4)	
User entered 'Yes (Y)'	Son Do (b) (4)	09 Mar 2021 16:33:19

US3642076

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:13:13

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	07 Apr 2021 10:10:05
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'data are correct. visit was erroneously conducted early due to coordinator scheduling error.' (Site from System).	Megan Loughran (b) (4)	05 Apr 2021 16:37:35
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	05 Apr 2021 16:37:11
User entered '05 Mar 2021' reason for change: Data Entry Error	Megan Loughran (b) (4)	05 Apr 2021 16:37:11
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	05 Apr 2021 16:33:47
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	05 Apr 2021 16:33:47
User entered empty; reason for change Data Entry Error	Megan Loughran (b) (4)	05 Apr 2021 16:33:47
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	09 Mar 2021 16:33:19
User entered '05 Mar 2021'	Son Do (b) (4)	09 Mar 2021 16:33:19

US3642076

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:13:13

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Clinic (Clinic)' reason for change:	Megan Loughran (b) (4)	05 Apr 2021 16:37:11
Data Entry Error	(b) (4)	
User entered empty; reason for change Data Entry	Megan Loughran (b) (4)	05 Apr 2021 16:33:47
Error	(b) (4)	
User entered 'Clinic (Clinic)'	Son Do (b) (4)	09 Mar 2021 16:33:19

**US3642076**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User entered 'VISIT4'	System	05 Apr 2021 16:37:11
User entered empty.	System	05 Apr 2021 16:33:47
User entered 'VISIT4'	System	09 Mar 2021 16:33:19

US3642076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
	(b) (4)	
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 16:37:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 16:37:00
User entered 'No (N)' reason for change: Data Entry Error	Megan Loughran (b) (4)	05 Apr 2021 16:37:00
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 16:33:55
Signature has been broken.	Megan Loughran (b) (4)	05 Apr 2021 16:33:55
	(b) (4)	
User entered empty; reason for change Data Entry Error	Megan Loughran (b) (4)	05 Apr 2021 16:33:55
	(b) (4)	
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:56
	(b) (4)	
User entered 'No (N)'	Benjamin Hull (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	

US3642076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:56
	(b) (4)	
User entered empty.	Benjamin Hull (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	

US3642076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:56
	(b) (4)	
User entered empty.	Benjamin Hull (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	



**US3642076**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User entered empty.	System	30 Mar 2021 19:54:21

US3642076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:56
	(b) (4)	
User entered empty.	Benjamin Hull (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	

US3642076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:56
	(b) (4)	
User entered empty.	Benjamin Hull (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	

US3642076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:56
	(b) (4)	
User entered empty.	Benjamin Hull (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	

US3642076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:56
	(b) (4)	
User entered empty.	Benjamin Hull (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	

**US3642076**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User entered empty.	System	30 Mar 2021 19:54:21

US3642076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:56
	(b) (4)	
User entered empty.	Benjamin Hull (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	

**US3642076**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User entered empty.	System	30 Mar 2021 19:54:21



US3642076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:56
	(b) (4)	
User entered empty.	Benjamin Hull (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	

**US3642076**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User entered empty.	System	30 Mar 2021 19:54:21

US3642076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:56
	(b) (4)	
User entered empty.	Benjamin Hull (b) (4)	30 Mar 2021 19:54:21
	(b) (4)	

**US3642076**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User entered empty.	System	30 Mar 2021 19:54:21

**US3642076**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39

US3642076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39

US3642076

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:13

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 16:36:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 16:36:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Megan Loughran (b) (4)	05 Apr 2021 16:36:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 16:34:08
Signature has been broken.	Megan Loughran (b) (4)	05 Apr 2021 16:34:08
	(b) (4)	
User entered empty; reason for change Data Entry Error	Megan Loughran (b) (4)	05 Apr 2021 16:34:08
	(b) (4)	
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
	(b) (4)	
User entered 'Yes (Y)'	Son Do (b) (4)	09 Mar 2021 16:33:56

US3642076

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '05 Mar 2021' reason for change: Data Entry Error	Megan Loughran (b) (4)	05 Apr 2021 16:36:53
	(b) (4)	
Signature has been broken.	Megan Loughran (b) (4)	05 Apr 2021 16:34:08
	(b) (4)	
User entered empty; reason for change Data Entry Error	Megan Loughran (b) (4)	05 Apr 2021 16:34:08
	(b) (4)	
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
	(b) (4)	
User entered '05 Mar 2021'	Son Do (b) (4)	09 Mar 2021 16:33:56



US3642076

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 16:36:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 16:36:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Megan Loughran (b) (4)	05 Apr 2021 16:36:40
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 16:34:24
Signature has been broken.	Megan Loughran (b) (4)	05 Apr 2021 16:34:24
	(b) (4)	
User entered empty; reason for change Data Entry Error	Megan Loughran (b) (4)	05 Apr 2021 16:34:24
	(b) (4)	
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
	(b) (4)	
User entered 'Yes (Y)'	Son Do (b) (4)	09 Mar 2021 16:34:13

US3642076

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:13

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
	(b) (4)	
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '05 Mar 2021' reason for change: Data Entry Error	Megan Loughran (b) (4)	05 Apr 2021 16:36:40
	(b) (4)	
Signature has been broken.	Megan Loughran (b) (4)	05 Apr 2021 16:34:24
	(b) (4)	
User entered empty; reason for change Data Entry Error	Megan Loughran (b) (4)	05 Apr 2021 16:34:24
	(b) (4)	
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
	(b) (4)	
User entered '05 Mar 2021'	Son Do (b) (4)	09 Mar 2021 16:34:13

US3642076

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
	(b) (4)	
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '15:17' reason for change: Data Entry Error	Megan Loughran (b) (4)	05 Apr 2021 16:36:40
	(b) (4)	
Signature has been broken.	Megan Loughran (b) (4)	05 Apr 2021 16:34:24
	(b) (4)	
User entered empty; reason for change Data Entry Error	Megan Loughran (b) (4)	05 Apr 2021 16:34:24
	(b) (4)	
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
	(b) (4)	
User entered '15:17'	Son Do (b) (4)	09 Mar 2021 16:34:13

**US3642076**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User entered '05 Mar 2021 15:17'	System	05 Apr 2021 16:36:40
User entered empty.	System	05 Apr 2021 16:34:24
User entered '05 Mar 2021 15:17'	System	09 Mar 2021 16:34:13

US3642076

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 16:36:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 16:36:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Megan Loughran (b) (4)	05 Apr 2021 16:36:12
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 16:34:31
Signature has been broken.	Megan Loughran (b) (4)	05 Apr 2021 16:34:31
	(b) (4)	
User entered empty; reason for change Data Entry Error	Megan Loughran (b) (4)	05 Apr 2021 16:34:31
	(b) (4)	
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
	(b) (4)	
User entered 'Yes (Y)'	Son Do (b) (4)	09 Mar 2021 16:34:18

US3642076

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:55:39
User entered '1'	System	05 Apr 2021 16:36:12
User entered empty.	System	05 Apr 2021 16:34:31
User entered '1'	System	09 Mar 2021 16:34:18

**US3642076**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 May 2021 21:24:09
	(b) (4)	
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	30 Apr 2021 22:39:32
	(b) (4)	

US3642076

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 May 2021 21:24:09
	(b) (4)	
User entered '30 Apr 2021'	Colleen McLellan (b) (4)	30 Apr 2021 22:39:32
	(b) (4)	



**US3642076**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 May 2021 21:24:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Colleen McLellan (b) (4)	30 Apr 2021 22:39:32
	(b) (4)	

**US3642076**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 May 2021 21:24:09
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	30 Apr 2021 22:39:32
	(b) (4)	

US3642076

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 May 2021 21:24:09
	(b) (4)	
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	30 Apr 2021 22:39:37
	(b) (4)	

**US3642076**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 22:39:37

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	Son Do (b) (4)	25 Jan 2021 19:17:02

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '21 Jan 2021'	Son Do (b) (4)	25 Jan 2021 19:17:02

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Clinic (Clinic)'	Son Do (b) (4)	25 Jan 2021 19:17:02

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 19:17:02



US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:13:13

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '21 Jan 2021'	Son Do (b) (4)	25 Jan 2021 19:17:20

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:13**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:18:50

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:13**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	Son Do (b) (4)	25 Jan 2021 19:17:20

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:13**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:18:50

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:13:13

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 10:52:23
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Data are correct. Subject unblinding occurred prior to date of consent form. PD reported.' (Site from System).	Colleen McLellan (b) (4) (b) (4)	26 Jan 2021 22:55:20
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	25 Jan 2021 19:17:20
User entered '08 Jan 2021'	Son Do (b) (4)	25 Jan 2021 19:17:20

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:13:13

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Placebo (Placebo)'	Son Do (b) (4)	25 Jan 2021 19:17:20

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:13**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Placebo (Placebo)'	Son Do (b) (4)	25 Jan 2021 19:17:20

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:13**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Placebo (Placebo)'	Son Do (b) (4)	25 Jan 2021 19:17:20



US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:13:13

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	Son Do (b) (4)	25 Jan 2021 19:17:20

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:13**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered '1'	System	25 Jan 2021 19:17:20

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:13**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'I'	System	25 Jan 2021 19:17:20

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:13**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered missing code ND - Not Done.	Son Do (b) (4)	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered missing code ND - Not Done.	Son Do (b) (4)	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered empty.	System	25 Jan 2021 19:18:08
DataPoint set to visible.	System	25 Jan 2021 19:17:20

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered missing code ND - Not Done.	Son Do (b) (4)	25 Jan 2021 19:18:08

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:13**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered missing code ND - Not Done.	Son Do (b) (4)	25 Jan 2021 19:18:08



US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered empty.	System	25 Jan 2021 19:18:08
DataPoint set to visible.	System	25 Jan 2021 19:17:20

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	Son Do (b) (4)	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '21 Jan 2021'	Son Do (b) (4)	25 Jan 2021 19:18:08

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '09:09'	Son Do (b) (4)	25 Jan 2021 19:18:08

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered '21 Jan 2021 09:09'	System	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '98.3' F	Son Do (b) (4)	25 Jan 2021 19:18:08

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Oral (Oral)'	Son Do (b) (4)	25 Jan 2021 19:18:08



US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	Son Do (b) (4)	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '119'	Son Do (b) (4)	25 Jan 2021 19:18:08

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'bpm'	System	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '16'	Son Do (b) (4)	25 Jan 2021 19:18:08

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'breaths/min'	System	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '128'	Son Do (b) (4)	25 Jan 2021 19:18:08

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'mmHg'	System	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:13

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '87'	Son Do (b) (4)	25 Jan 2021 19:18:08



**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'mmHg'	System	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered missing code ND - Not Done.	Son Do (b) (4)	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered missing code ND - Not Done.	Son Do (b) (4)	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered empty.	System	25 Jan 2021 19:18:08
DataPoint set to visible.	System	25 Jan 2021 19:17:20

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	Son Do (b) (4)	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '21 Jan 2021'	Son Do (b) (4)	25 Jan 2021 19:18:08

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '10:30'	Son Do (b) (4)	25 Jan 2021 19:18:08



**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered '21 Jan 2021 10:30'	System	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '98.3' F	Son Do (b) (4)	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Oral (Oral)'	Son Do (b) (4)	25 Jan 2021 19:18:08

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	Son Do (b) (4)	25 Jan 2021 19:18:08

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '114'	Son Do (b) (4)	25 Jan 2021 19:18:08

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'bpm'	System	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '16'	Son Do (b) (4)	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'breaths/min'	System	25 Jan 2021 19:18:08



US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '116'	Son Do (b) (4)	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'mmHg'	System	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '81'	Son Do (b) (4)	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'mmHg'	System	25 Jan 2021 19:18:08

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	Son Do (b) (4)	25 Jan 2021 19:18:14

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:13**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	Son Do (b) (4)	25 Jan 2021 19:18:14

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	Son Do (b) (4)	25 Jan 2021 19:18:28

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	Son Do (b) (4)	25 Jan 2021 19:18:28



US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

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 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	Son Do (b) (4)	25 Jan 2021 19:18:28

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'mRNA-1273'	System	25 Jan 2021 19:18:28
DataPoint set to visible.	System	25 Jan 2021 19:17:20

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '21 Jan 2021'	Son Do (b) (4)	25 Jan 2021 19:18:28

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '09:59'	Son Do (b) (4)	25 Jan 2021 19:18:28

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:13**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered '21 Jan 2021 09:59'	System	25 Jan 2021 19:18:28

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Left Arm (LEFT ARM)'	Son Do (b) (4)	25 Jan 2021 19:18:28

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'ONCE'	System	25 Jan 2021 19:18:28

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:13**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'INTRAMUSCULAR'	System	25 Jan 2021 19:18:28



**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	Son Do (b) (4)	25 Jan 2021 19:18:46

US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:13:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '21 Jan 2021'	Son Do (b) (4)	25 Jan 2021 19:18:46

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:13**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '09:45'	Son Do (b) (4)	25 Jan 2021 19:18:46

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered '21 Jan 2021 09:45'	System	25 Jan 2021 19:18:46

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:13:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	Son Do (b) (4)	25 Jan 2021 19:18:56

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:13:13**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '21 Jan 2021'	Son Do (b) (4)	25 Jan 2021 19:18:56

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:13:13**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '09:47'	Son Do (b) (4)	25 Jan 2021 19:18:56

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:13:13**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered '21 Jan 2021 09:47'	System	25 Jan 2021 19:18:56



US3642076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	Son Do (b) (4)	25 Jan 2021 19:19:01

**US3642076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'I'	System	25 Jan 2021 19:19:01

**US3642076**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 23:59:49
User entered 'No (N)'	Lindsey Woronicz (b) (4)	30 Jan 2021 01:26:28

**US3642076**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered '29 Jan 2021' reason for change: Data Entry Error	(b) (4)	01 Feb 2021 23:59:49
User entered empty.	Lindsey Woronicz (b) (4)	30 Jan 2021 01:26:28

**US3642076**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	01 Feb 2021 23:59:49
reason for change: Data Entry Error	Lindsey Woronicz (b) (4)	01 Feb 2021 23:59:49
User entered empty.	Lindsey Woronicz (b) (4)	30 Jan 2021 01:26:28

**US3642076**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered empty.	(b) (4) Lindsey Woronicz (b) (4)	30 Jan 2021 01:26:28

**US3642076**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:55
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	30 Jan 2021 01:26:32

**US3642076**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'I'	System	30 Jan 2021 01:26:32



**US3642076**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered '1'	System	30 Jan 2021 01:26:32
DataPoint set to visible.	System	30 Jan 2021 01:26:32

**US3642076**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered 'Yes (Y)'	Son Do (b) (4)	09 Mar 2021 16:13:02

US3642076

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:13:13

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	15 Mar 2021 10:51:38
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'participant was in the hospital at time of visit window due to new AE of cough/nausea. Unable to attend visit during scheduled window. PD has been filed, and source includes note.' (Site from System).	(b) (4)	
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	Megan Loughran (b) (4)	12 Mar 2021 20:27:34
User entered '05 Mar 2021'	(b) (4)	
	System	09 Mar 2021 16:13:02
	Son Do (b) (4)	09 Mar 2021 16:13:02

**US3642076**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered 'Clinic (Clinic)'	Son Do (b) (4)	09 Mar 2021 16:13:02

**US3642076**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'OLD29'	System	09 Mar 2021 16:13:02

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered 'Yes (Y)'	Son Do (b) (4)	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered '05 Mar 2021'	Son Do (b) (4)	09 Mar 2021 16:13:50



**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered '14:16'	Son Do (b) (4)	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered '05 Mar 2021 14:16'	System	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered '98.5' F	Son Do (b) (4)	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered 'Oral (Oral)'	Son Do (b) (4)	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered empty.	Son Do (b) (4)	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered '93'	Son Do (b) (4)	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'bpm'	System	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered '18'	Son Do (b) (4)	09 Mar 2021 16:13:50



**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'breaths/min'	System	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered '136'	(b) (4) Son Do (b) (4)	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'mmHg'	System	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered '88'	Son Do (b) (4)	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'mmHg'	System	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered 'Yes (Y)'	Son Do (b) (4)	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered '05 Mar 2021'	Son Do (b) (4)	09 Mar 2021 16:13:50



**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered '16:06'	Son Do (b) (4)	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered '05 Mar 2021 16:06'	System	09 Mar 2021 16:13:50

US3642076

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered '98.3' F	Son Do (b) (4)	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered 'Oral (Oral)'	(b) (4) Son Do (b) (4)	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered empty.	Son Do (b) (4)	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered '95'	Son Do (b) (4)	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'bpm'	System	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered '16'	(b) (4) Son Do (b) (4)	09 Mar 2021 16:13:50



**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'breaths/min'	System	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered '160'	(b) (4) Son Do (b) (4)	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'mmHg'	System	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered '102'	(b) (4) Son Do (b) (4)	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'mmHg'	System	09 Mar 2021 16:13:50

**US3642076**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:13**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered 'Yes (Y)'	Son Do (b) (4)	09 Mar 2021 16:14:01

**US3642076**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:13**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered '05 Mar 2021'	Son Do (b) (4)	09 Mar 2021 16:14:01

**US3642076**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:13**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered 'Yes (Y)'	Son Do (b) (4)	09 Mar 2021 16:14:20



**US3642076**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:13**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered empty.	Son Do (b) (4)	09 Mar 2021 16:14:20

US3642076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

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 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered empty.	Son Do (b) (4)	09 Mar 2021 16:14:20

**US3642076**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:13**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'mRNA-1273'	System	09 Mar 2021 16:14:20
DataPoint set to visible.	System	30 Jan 2021 01:26:32

US3642076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered '05 Mar 2021'	Son Do (b) (4)	09 Mar 2021 16:14:20

US3642076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered '15:33'	Son Do (b) (4)	09 Mar 2021 16:14:20

**US3642076**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:13**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered '05 Mar 2021 15:33'	System	09 Mar 2021 16:14:20

US3642076

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered 'Left Arm (LEFT ARM)'	Son Do (b) (4)	09 Mar 2021 16:14:20

**US3642076**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:13**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'ONCE'	System	09 Mar 2021 16:14:20



**US3642076**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:13**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'INTRAMUSCULAR'	System	09 Mar 2021 16:14:20

**US3642076**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered 'Yes (Y)'	Son Do (b) (4)	09 Mar 2021 16:14:26

**US3642076**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'I'	System	09 Mar 2021 16:14:26

**US3642076**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:25:12

**US3642076**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:25:12

**US3642076**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:25:12

**US3642076**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:13**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:25:12

**US3642076**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:56
User entered 'Yes (Y)'	Son Do (b) (4)	09 Mar 2021 16:32:11



**US3642076**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:13**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:08:57
User entered 'I'	System	09 Mar 2021 16:32:11

**US3642076**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Yes (Y)'	Son Do (b) (4)	06 Apr 2021 17:15:24

**US3642076**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered '05 Apr 2021'	(b) (4) Son Do (b) (4)	06 Apr 2021 17:15:24

**US3642076**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered 'Clinic (Clinic)'	(b) (4) Son Do (b) (4)	06 Apr 2021 17:15:24

**US3642076**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:13**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	06 Apr 2021 17:15:24

**US3642076**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered 'No (N)'	(b) (4) Son Do (b) (4)	06 Apr 2021 17:15:31

**US3642076**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered empty.	(b) (4) Son Do (b) (4)	06 Apr 2021 17:15:31

**US3642076**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered empty.	(b) (4) Son Do (b) (4)	06 Apr 2021 17:15:31



**US3642076**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:15:31

US3642076

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:13

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered empty.	(b) (4) Son Do (b) (4)	06 Apr 2021 17:15:31

**US3642076**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered empty.	(b) (4) Son Do (b) (4)	06 Apr 2021 17:15:31

**US3642076**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered empty.	(b) (4) Son Do (b) (4)	06 Apr 2021 17:15:31

**US3642076**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered empty.	(b) (4) Son Do (b) (4)	06 Apr 2021 17:15:31

**US3642076**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:15:31

**US3642076**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered empty.	(b) (4) Son Do (b) (4)	06 Apr 2021 17:15:31

**US3642076**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:15:31



**US3642076**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered empty.	(b) (4) Son Do (b) (4)	06 Apr 2021 17:15:31

**US3642076**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:15:31

**US3642076**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered empty.	(b) (4) Son Do (b) (4)	06 Apr 2021 17:15:31

**US3642076**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:13**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:15:31

**US3642076**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:13**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'No (N)'	Son Do (b) (4)	06 Apr 2021 17:15:36

**US3642076**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:13**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Son Do (b) (4)	06 Apr 2021 17:15:36

**US3642076**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:13**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	06 Apr 2021 17:15:49

**US3642076**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:13**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered '05 Apr 2021'	(b) (4) Son Do (b) (4)	06 Apr 2021 17:15:49



**US3642076**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:13**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered '15:37'	(b) (4) Son Do (b) (4)	06 Apr 2021 17:15:49

**US3642076**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:13**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '05 Apr 2021 15:37'	System	06 Apr 2021 17:15:49

US3642076

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:13:13

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:13:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Signature has been broken.	(b) (4) Nancy Tang (b) (4)	01 Mar 2021 22:30:44
User entered 'Yes (Y)' reason for change: New Information	Nancy Tang (b) (4)	01 Mar 2021 22:30:44
User signature succeeded.	(b) (4) Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:50:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 15:18:09
User entered 'USA-US109-2021-mRNA-1273-P301000007'		02 Mar 2021 15:18:04

US3642076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:13

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Metastases, HLT: Metastases to specified sites, PT: Metastases to lung, LLT: Metastases to lung - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 17:52:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 17:52:33
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:27:56
Data point term sent to Coder	System	15 Mar 2021 22:08:26
Coding entries removed.	Nancy Tang (b) (4) (b) (4)	15 Mar 2021 22:07:34
Signature has been broken.	Nancy Tang (b) (4) (b) (4)	15 Mar 2021 22:07:34
User entered 'POSSIBLE RELAPSE OF RENAL CELL CARCINOMA METASTASIZED TO HIS LUNGS' reason for change: Data Entry Error	Nancy Tang (b) (4) (b) (4)	15 Mar 2021 22:07:34
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:40:33
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Renal and urinary tract neoplasms malignant and unspecified, HLT: Renal neoplasms malignant, PT: Metastatic renal cell carcinoma, LLT: Metastatic renal cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 05:38:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 05:38:09
Data point term sent to Coder	System	01 Mar 2021 22:46:48
User entered 'Relapse of renal cell carcinoma metastasized to his lungs'	Nancy Tang (b) (4) (b) (4)	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered 'Yes (Y)'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered 'No (N)'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19

US3642076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered 'No (N)'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19



**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered '22 Feb 2021'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered 'Yes (Y)'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:02:00
Signature has been broken.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:26:58
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
User entered empty.	(b) (4) Nancy Tang (b) (4)	01 Mar 2021 22:46:19

US3642076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:13

End time (00:00-23:59)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date for the event, 'possible relapse of renal cell carcinoma metastasized to his lungs', when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available. ? ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:35:48
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
User entered empty.	(b) (4) Nancy Tang (b) (4)	01 Mar 2021 22:46:19

US3642076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Re-Query: Please provide the event end date for the event, 'possible relapse of renal cell carcinoma metastasized to his lungs', when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:35:30
Query 'PV Query: Please provide the event end date for the event, 'possible relapse of renal cell carcinoma metastasized to his lungs', when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' canceled (Site from Safety).		23 Apr 2021 17:57:30
User opened query 'PV Re-Query: Please provide the event end date for the event, 'possible relapse of renal cell carcinoma metastasized to his lungs', when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available' (Site from Safety).		23 Apr 2021 17:57:24
User opened query 'PV Query: Please provide the event end date for the event, 'possible relapse of renal cell carcinoma metastasized to his lungs', when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).		14 Apr 2021 18:49:54
User entered empty.	System	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Nancy Tang (b) (4)	01 Mar 2021 22:46:19



US3642076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered 'Yes (Y)'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered '0'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered 'I'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19

US3642076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	01 Mar 2021 22:46:33
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	01 Mar 2021 22:46:33
User entered '1' reason for change: Data Entry Error	Nancy Tang (b) (4)	01 Mar 2021 22:46:33
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	01 Mar 2021 22:46:19
User entered '0'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19

US3642076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered '22 Feb 2021'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19

US3642076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:13

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered '24 Feb 2021'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered 'No (N)'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	01 Mar 2021 22:46:19



US3642076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered '0'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered '0'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered '0'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered 'None (NONE)'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:02:00
	(b) (4)	
Signature has been broken.	Nancy Tang (b) (4)	15 Apr 2021 21:05:42
	(b) (4)	
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered '0'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19
	(b) (4)	

US3642076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:02:00
	(b) (4)	
Signature has been broken.	Nancy Tang (b) (4)	15 Apr 2021 21:07:05
	(b) (4)	
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered 'l'	Nancy Tang (b) (4)	01 Mar 2021 22:46:19
	(b) (4)	



US3642076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:02:00
Signature has been broken.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:26:20
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).		26 Mar 2021 16:42:59
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with ' CT SCAN OF ABDOMEN AND THE BRAIN was completed. See Concomitant Procedure.' (Site from DM).	Nancy Tang (b) (4)	24 Mar 2021 23:21:13
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 08:55:16
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
User entered 'I'	(b) (4) Nancy Tang (b) (4)	01 Mar 2021 22:46:19

US3642076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:13:13

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final outcome for the event, 'possible relapse of renal cell carcinoma metastasized to his lungs' when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. .' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 17:58:37
User closed query 'PV Query: Please provide the final outcome for the event, 'possible relapse of renal cell carcinoma metastasized to his lungs' when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. .' (Site from Safety).		16 Apr 2021 15:35:13
Query 'PV Query: Please provide the final outcome for the event, 'possible relapse of renal cell carcinoma metastasized to his lungs' when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. .' answered with 'Subject reports that his symptoms have stabilized with medications. He will follow up with palliative team and update study team member of any changes to his plan of care.' (Site from Safety).	Nancy Tang (b) (4)	15 Apr 2021 21:12:40
User opened query 'PV Query: Please provide the final outcome for the event, 'possible relapse of renal cell carcinoma metastasized to his lungs' when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. .' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 18:50:19
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Nancy Tang (b) (4)	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
User entered 'Subject was hospitalized for 2 days for observation due to symptoms indicating relapse of renal cell carcinoma metastasized to his lungs. He was diagnosed with Renal cell carcinoma 2015 and was off treatment since 2019. Subject will continue to remain in the study and wants to continue getting second immunization.'	(b) (4) Nancy Tang (b) (4)	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Mar 2021 22:46:19

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Mar 2021 22:46:19

US3642076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:13:13

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 17:09:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 17:09:48
Data point term sent to Coder	System	06 Apr 2021 17:08:56
User entered 'COUGH'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30



**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '24 Feb 2021'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:08:30

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	



**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 17:08:30

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

US3642076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:13:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 17:08:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Apr 2021 17:08:36
User entered 'No (N)' reason for change: Data Entry Error	Colleen McLellan (b) (4)	06 Apr 2021 17:08:36
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 17:08:30
User entered empty.	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

US3642076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:13:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	



US3642076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:13:13

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

US3642076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:13:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

US3642076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:13:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	



**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

US3642076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:13:13

None

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Apr 2021 17:08:44
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Apr 2021 17:08:30
User entered '0'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

US3642076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:13:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Colleen McLellan (b) (4)	06 Apr 2021 17:08:44
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30
	(b) (4)	

US3642076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:13:13

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered 'PATIENT DISCHARGED FROM HOSPITAL AFTER OVERNIGHT STAY FOR UNCONTROLLED COUGH (SEE PREVIOUS RESOLVED AE LOG LINE3). COUGH NOW CONTROLLED AND HE WAS DISCHARGD HOME ON PO GUAIFENESIN (EXTENDED RELEASE) AND BENZONATATE. UPDATE: HE REPORTS THAT HE HAS STOPPED TAKING BENZONATATE AND GUIFENESIN AS OF 01APR2021. HE HAS NOT FOLLOWED UP WITH ANY OF HIS MEDICAL TEAM BUT HAS AN APPOINTMENT SCHEDULED WITH PALLIATIVE CARE ON 06APR2021. HE WAS INSTRUCTED TO UPDATE THE STUDY TEAM AFTER HIS PALLIATIVE CARE APPOINTMENT.'	(b) (4)	
	Colleen McLellan (b) (4)	06 Apr 2021 17:08:30

**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Apr 2021 17:08:36



**US3642076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 17:08:30

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:13:13

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:13:48
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	Son Do (b) (4)	23 Sep 2020 16:44:20

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Feb 2021 22:56:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 22:56:29
Data point term sent to Coder Coding entries removed.	System Colleen McLellan (b) (4)	04 Feb 2021 22:55:45 04 Feb 2021 22:55:19
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 16:45:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 16:45:45
Data point term sent to Coder User entered 'xarelto'	System Son Do (b) (4)	23 Sep 2020 16:45:03 23 Sep 2020 16:44:54

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:44:54

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 08:39:32
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'UPDATED PER QUERY ' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	04 Feb 2021 22:55:31
User entered 'HISTORY OF BLOOD CLOTS' reason for change: Per Query Resolution	Colleen McLellan (b) (4) (b) (4)	04 Feb 2021 22:55:19
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 18:25:50
User entered 'blood thinner'	Son Do (b) (4)	23 Sep 2020 16:44:54

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '20'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:44:54

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'mg (mg)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:44:54

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:44:54



US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'once daily (QD)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:44:54

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:44:54

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:44:54

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:44:54

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'UN UNK 2018'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:44:54

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '0'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:44:54

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:44:54

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:44:54



US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:44:54

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:44:54

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:44:54

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 16:44:54

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Feb 2021 22:57:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 22:57:29
Data point term sent to Coder Coding entries removed.	System Colleen McLellan (b) (4)	04 Feb 2021 22:56:46 04 Feb 2021 22:56:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Sep 2020 00:31:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 00:31:44
Data point term sent to Coder User entered 'mirtazapine'	System Son Do (b) (4)	23 Sep 2020 16:46:06 23 Sep 2020 16:45:26

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:26

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 08:40:19
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'UPDATED PER REQUEST ' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	04 Feb 2021 22:56:11
User entered 'DEPRESSION' reason for change: Per Query Resolution	Colleen McLellan (b) (4) (b) (4)	04 Feb 2021 22:56:00
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 18:27:18
User entered 'anti depressant'	Son Do (b) (4)	23 Sep 2020 16:45:26

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '30'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:26



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'mg (mg)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:26

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:26

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'once daily (QD)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:26

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:26

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:26

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:26

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'UN UNK 2016'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:26

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '0'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:26



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:26

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:26

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:26

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:45:26

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:45:26

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 16:45:26

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Sep 2020 16:46:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 16:46:52
Data point term sent to Coder	System	23 Sep 2020 16:46:07
User entered 'atorvastatin'	Son Do (b) (4)	23 Sep 2020 16:45:57

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:57



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'hyperlipidemia'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:57

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '40'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:57

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'mg (mg)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:57

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:57

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'once daily (QD)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:57

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:57

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:57

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:57



US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'UN UNK 2018'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:57

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '0'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:57

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:57

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:57

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:45:57

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:45:57

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:45:57

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 16:45:57



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VORTIOXETINE HYDROBROMIDE, PRODUCTSYNONYM: TRINTELLIX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Feb 2021 22:59:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 22:59:29
Data point term sent to Coder Coding entries removed.	System Colleen McLellan (b) (4)	04 Feb 2021 22:58:47 04 Feb 2021 22:57:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VORTIOXETINE HYDROBROMIDE, PRODUCTSYNONYM: TRINTELLIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 16:47:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 16:47:39
Data point term sent to Coder User entered 'trintellix'	System Son Do (b) (4)	23 Sep 2020 16:47:08 23 Sep 2020 16:46:27

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:27

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 08:40:59
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'UPDATED PER REQUEST ' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	04 Feb 2021 22:58:01
User entered 'DEPRESSION' reason for change: Per Query Resolution	Colleen McLellan (b) (4) (b) (4)	04 Feb 2021 22:57:54
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 18:28:00
User entered 'anti depressant'	Son Do (b) (4)	23 Sep 2020 16:46:27

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '10'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:27

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'mg (mg)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:27

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:27

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'once daily (QD)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:27

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:27



US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:27

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:27

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'UN UNK 2018'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:27

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:13

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '0'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:27

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:27

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:27

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:27

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:46:27



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:46:27

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 16:46:27

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: DOXAZOSIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Feb 2021 09:17:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 09:17:52
Data point term sent to Coder Coding entries removed.	System Colleen McLellan (b) (4)	04 Feb 2021 23:02:54 04 Feb 2021 23:02:30
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: DOXAZOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 22:55:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 22:55:46
Data point term sent to Coder User entered 'doxazusin'	System Son Do (b) (4)	23 Sep 2020 16:47:11 23 Sep 2020 16:46:56

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:56

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 08:43:38
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'PATIENT REPORTS UNSPECIFIED "PROSTATE ISSUE" IN MEDICAL HISTORY ASSOCIATED WITH THIS MEDICATION' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	04 Feb 2021 23:02:59
User entered 'PROSTATE ISSUE' reason for change: Per Query Resolution	Colleen McLellan (b) (4) (b) (4)	04 Feb 2021 23:02:30
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 18:30:32
User entered 'uretic'	Son Do (b) (4)	23 Sep 2020 16:46:56

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '2'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:56

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'mg (mg)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:56

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:56



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'once daily (QD)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:56

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:56

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:56

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:56

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'UN UNK 2010'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:56

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '0'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:56

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:56

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:56



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:46:56

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:46:56

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:46:56

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 16:46:56

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, OTHER COMBINATIONS, PRODUCT: ASCORBIC ACID;BIOTIN;CALCIUM PANTOTHENATE;CALCIUM PHOSPHATE DIBASIC;CYANOCOBALAMIN;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE;YEAST DRIED, PRODUCTSYNONYM: NATURE MADE SUPER B COMPLEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 16:49:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 16:49:36
Data point term sent to Coder	System	23 Sep 2020 16:48:12
User entered 'nature made super b complex'	Son Do (b) (4)	23 Sep 2020 16:47:29

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Megan Loughran (b) (4)	01 Feb 2021 21:14:16
	(b) (4)	
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:47:29

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:13**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'supplement'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:47:29

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '1'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:47:29



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:13**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'tablet (TABLET)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:47:29

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:47:29

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'once daily (QD)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:47:29

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:13**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:47:29

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:47:29

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:47:29

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'UN UNK 2019'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:47:29

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '0'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:47:29



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:47:29

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:47:29

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:47:29

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:47:29

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:47:29

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 16:47:29

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID, PRODUCTSYNONYM: FOLATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Sep 2020 16:49:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 16:49:35
Data point term sent to Coder	System	23 Sep 2020 16:48:13
User entered 'folate'	Son Do (b) (4)	23 Sep 2020 16:48:00

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Megan Loughran (b) (4)	01 Feb 2021 21:14:26
	(b) (4)	
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:48:00



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:13**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'supplement'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:00

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '400'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:00

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:13**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Colleen McLellan (b) (4)	04 Feb 2021 23:04:20
	(b) (4)	
User entered 'Other (OTHER)'	Son Do (b) (4)	23 Sep 2020 16:48:00

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User closed query 'Per CDM: "Dose unit - Other" is recorded as "MCG" as there is an available option for "micrograms (mcg) = ug" in the listed choices for "Dose unit". Please review and select an appropriate option from the drop-down list and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 04:56:08
Query 'Per CDM: "Dose unit - Other" is recorded as "MCG" as there is an available option for "micrograms (mcg) = ug" in the listed choices for "Dose unit". Please review and select an appropriate option from the drop-down list and update accordingly.' answered with 'CORRECTED PER REQUEST ' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	04 Feb 2021 23:04:34
User entered empty; reason for change Data Entry Error	Colleen McLellan (b) (4) (b) (4)	04 Feb 2021 23:04:20
User opened query 'Per CDM: "Dose unit - Other" is recorded as "MCG" as there is an available option for "micrograms (mcg) = ug" in the listed choices for "Dose unit". Please review and select an appropriate option from the drop-down list and update accordingly.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:24:58
User entered 'mcg'	Son Do (b) (4)	23 Sep 2020 16:48:00

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'once daily (QD)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:00

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:00

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:00

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:00



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'UN UNK 2019'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:00

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '0'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:00

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:00

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:00

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:00

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:48:00

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:48:00

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 16:48:00



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON HYDROCHLORIDE, PRODUCTSYNONYM: ONDANSETRON ODT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Feb 2021 23:07:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 23:07:29
Data point term sent to Coder Coding entries removed.	System Colleen McLellan (b) (4)	04 Feb 2021 23:06:55 04 Feb 2021 23:06:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON HYDROCHLORIDE, PRODUCTSYNONYM: ONDANSETRON ODT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 16:50:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 16:50:40
Data point term sent to Coder User entered 'ondansetron odt'	System Son Do (b) (4)	23 Sep 2020 16:49:14 23 Sep 2020 16:48:33

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:33

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:13

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF (NAUSEA). Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 13:59:48
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF (NAUSEA). Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'Nausea updated as medical history per query request' (Site from DM).	Nancy Tang (b) (4)	15 Mar 2021 21:46:22
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF (NAUSEA). Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 00:18:15
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 08:49:03
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' answered with 'ZOFRAN PRESCRIBED PRN, AS COMMON SIDE EFFECT OF OPDIVO IS NAUSEA' (Site from DM).	Colleen McLellan (b) (4)	04 Feb 2021 23:06:59
User entered 'NAUSEA R/T OPDIVO' reason for change: Per Query Resolution	Colleen McLellan (b) (4)	04 Feb 2021 23:06:31
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 19:16:17
User entered 'nausea'	Son Do (b) (4)	23 Sep 2020 16:48:33

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '4'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:33

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'mg (mg)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:33

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:33

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'as needed (PRN)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:33

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:33



US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:33

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:33

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered 'UN UNK 2018' reason for change: Data Entry Error	Colleen McLellan (b) (4)	04 Feb 2021 23:16:36
	(b) (4)	
User entered 'UN UNK 2019' reason for change: Data Entry Error	Colleen McLellan (b) (4)	04 Feb 2021 23:07:57
	(b) (4)	
User entered 'UN UNK 2018'	Son Do (b) (4)	23 Sep 2020 16:48:33

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '0'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:33

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:33

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:33

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:48:33

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 16:48:33



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 16:48:33

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 16:48:33

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Sep 2020 16:50:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 16:50:38
Data point term sent to Coder	System	23 Sep 2020 16:49:16
User entered 'acetaminophen'	Son Do (b) (4)	23 Sep 2020 16:49:04

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:49:04

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 08:49:40
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' answered with 'HEADACHCES ADDED TO MH' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	04 Feb 2021 23:18:01
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 19:17:15
User entered 'headache'	Son Do (b) (4)	23 Sep 2020 16:49:04

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '500'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:49:04

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'mg (mg)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:49:04

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:49:04



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'as needed (PRN)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:49:04

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:49:04

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:49:04

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:49:04

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'UN UNK 1980'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:49:04

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '0'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:49:04

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:49:04

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	23 Sep 2020 16:49:04



US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	(b) (4) Son Do (b) (4)	23 Sep 2020 16:49:04

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 16:49:04

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 16:49:04

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 16:49:04

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:49
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: MONOCLONAL ANTIBODIES, PRODUCT: NIVOLUMAB, PRODUCTSYNONYM: OPDIVO - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 23:11:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 23:11:32
Data point term sent to Coder Coding entries removed.	System Colleen McLellan (b) (4)	04 Feb 2021 23:10:57 04 Feb 2021 23:10:16
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: MONOCLONAL ANTIBODIES, PRODUCT: NIVOLUMAB, PRODUCTSYNONYM: OPDIVO - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Oct 2020 15:53:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Oct 2020 15:53:42
Data point term sent to Coder	System	02 Oct 2020 15:52:24
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	02 Oct 2020 15:52:09
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'spelling corrected' (Site from System).	Son Do (b) (4)	02 Oct 2020 15:52:09

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2076 of 2395

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:13

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'OPdIVO' reason for change: Data Entry Error	Son Do (b) (4)	02 Oct 2020 15:51:58
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	29 Sep 2020 07:59:46
Data point term sent to Coder	System	23 Sep 2020 16:50:18
User entered 'optivo'	Son Do (b) (4)	23 Sep 2020 16:50:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:49
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:50:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:49
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 08:50:22
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' answered with 'RENAL CELL CARCINOMA ADDED TO MH' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	04 Feb 2021 23:18:54
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF or add prophylaxis to indication.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 19:18:09
User entered 'renal cell carcinoma'	Son Do (b) (4)	23 Sep 2020 16:50:05



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:49
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User closed query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 08:51:08
Query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' answered with 'DOSE UNKNOWN PER SOURCE ' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	04 Feb 2021 23:09:18
User entered 'UNK' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	04 Feb 2021 23:09:01
User opened query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 19:18:45
User entered 'I'	Son Do (b) (4)	23 Sep 2020 16:50:05

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:13**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:49
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Other (OTHER)'	Son Do (b) (4)	23 Sep 2020 16:50:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:49
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User closed query ' Per DM CLR: Please review recorded Unit, Frequency and Route as these are not expected for this medication. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:56:29
Query ' Per DM CLR: Please review recorded Unit, Frequency and Route as these are not expected for this medication. Please review and update applicable details as appropriate. Otherwise, clarify.' answered with 'DOSE UNKNOWN PER SOURCE ' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	04 Feb 2021 23:09:25
User entered 'UNK' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	04 Feb 2021 23:09:01
User opened query ' Per DM CLR: Please review recorded Unit, Frequency and Route as these are not expected for this medication. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 18:54:40
User entered 'drop'	Son Do (b) (4)	23 Sep 2020 16:50:05

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:13**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:49
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'once daily (QD)'	Son Do (b) (4)	23 Sep 2020 16:50:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:49
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	Son Do (b) (4)	23 Sep 2020 16:50:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:49
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User closed query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please review and correct as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:56:31
Query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please review and correct as appropriate.' answered with 'CORRECTED PER SOURCE' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	04 Feb 2021 23:10:37
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	04 Feb 2021 23:10:16
User opened query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please review and correct as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 19:19:03
User entered 'Intraocular (INTRAOCULAR)'	Son Do (b) (4)	23 Sep 2020 16:50:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:49
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	Son Do (b) (4)	23 Sep 2020 16:50:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:49
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'UN UNK 2019'	Son Do (b) (4)	23 Sep 2020 16:50:05



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:49
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '0'	Son Do (b) (4)	23 Sep 2020 16:50:05

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:49
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:50:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:49
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'UN UNK 2019'	Son Do (b) (4)	23 Sep 2020 16:50:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:49
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:50:05

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:49
User entered '1'	System	23 Sep 2020 16:50:05

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:49
User entered '1'	System	23 Sep 2020 16:50:05

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:49
User entered '804 (804)'	System	23 Sep 2020 16:50:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: LAMOTRIGINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Nov 2020 22:30:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Nov 2020 22:30:02
Data point term sent to Coder	System	30 Nov 2020 22:29:44
User entered 'lamotrigine'	Benjamin Hull (b) (4) (b) (4)	30 Nov 2020 22:29:27



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered 'No (N)'	Benjamin Hull (b) (4)	30 Nov 2020 22:29:27
	(b) (4)	

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User closed query 'Per DM CLR: Was this medication added because the patients Med History of DEPRESSION worsened? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for the addition of the new medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 08:51:20
Query 'Per DM CLR: Was this medication added because the patients Med History of DEPRESSION worsened? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for the addition of the new medication. ' answered with 'PATIENT DOES NOT REPORT ANY WORSENING DEPRESSION MEETING THE CRITERIA FOR AE.' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	04 Feb 2021 23:25:04
User opened query 'Per DM CLR: Was this medication added because the patients Med History of DEPRESSION worsened? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for the addition of the new medication. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 12:50:14
User entered 'depression'	Benjamin Hull (b) (4) (b) (4)	30 Nov 2020 22:29:27

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '25'	(b) (4) Benjamin Hull (b) (4) (b) (4)	30 Nov 2020 22:29:27

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered 'mg (mg)'	Benjamin Hull (b) (4)	30 Nov 2020 22:29:27
	(b) (4)	

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered empty.	Benjamin Hull (b) (4)	30 Nov 2020 22:29:27
	(b) (4)	

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'once daily (QD)'	(b) (4) Benjamin Hull (b) (4) (b) (4)	30 Nov 2020 22:29:27

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered empty.	Benjamin Hull (b) (4)	30 Nov 2020 22:29:27
	(b) (4)	

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Oral (ORAL)'	(b) (4) Benjamin Hull (b) (4) (b) (4)	30 Nov 2020 22:29:27



US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered empty.	Benjamin Hull (b) (4)	30 Nov 2020 22:29:27
	(b) (4)	

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered '08 Sep 2020'	Benjamin Hull (b) (4)	30 Nov 2020 22:29:27
	(b) (4)	

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered '0'	Benjamin Hull (b) (4)	30 Nov 2020 22:29:27
	(b) (4)	

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	(b) (4) Benjamin Hull (b) (4)	30 Nov 2020 22:29:27

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered empty.	Benjamin Hull (b) (4)	30 Nov 2020 22:29:27
	(b) (4)	

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered 'No (N)'	Benjamin Hull (b) (4)	30 Nov 2020 22:29:27
	(b) (4)	

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Nov 2020 22:29:27

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Nov 2020 22:29:27



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Nov 2020 22:29:27

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:13

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: TIOTROPIUM BROMIDE, PRODUCTSYNONYM: SPIRIVA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 17:56:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 17:56:03
Data point term sent to Coder Coding entries removed.	System	31 Mar 2021 17:55:28
	Nancy Tang (b) (4)	31 Mar 2021 17:55:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: TIOTROPIUM BROMIDE, PRODUCTSYNONYM: SPIRIVA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 21:51:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 21:51:37
Data point term sent to Coder Coding entries removed.	System	15 Mar 2021 21:50:53
	Nancy Tang (b) (4)	15 Mar 2021 21:50:38
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: TIOTROPIUM BROMIDE, PRODUCTSYNONYM: SPIRIVA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 19:16:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 19:16:50
Data point term sent to Coder	System	25 Jan 2021 19:15:45

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:13**

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'spiriva'	Son Do (b) (4)	25 Jan 2021 19:14:50

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered 'No (N)'	Son Do (b) (4)	25 Jan 2021 19:14:50

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 09:52:17
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Sprivia was used to treat medical history of fatigue related to shortness of breath post metastatic renal cell carcinoma. See Medical history of Fatigue and Metastatic renal cell carcinoma.' (Site from DM).	Nancy Tang (b) (4)	31 Mar 2021 17:58:12
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 17:55:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 17:55:02
User entered 'FATIGUE RELATED TO SHORTNESS OF BREATH POST METASTATIC RENAL CELL CARCINOMA' reason for change: Data Entry Error	Nancy Tang (b) (4)	31 Mar 2021 17:55:02
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 21:50:38
Signature has been broken.	Nancy Tang (b) (4)	15 Mar 2021 21:50:38
User entered empty; reason for change Data Entry Error	Nancy Tang (b) (4)	15 Mar 2021 21:50:38
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 00:18:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'fatigue'	(b) (4) Son Do (b) (4)	25 Jan 2021 19:14:50

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered '18'	Son Do (b) (4)	25 Jan 2021 19:14:50

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 13:58:35
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'DOSAGE UPDATED PER QUERY REQUEST' (Site from DM).	Nancy Tang (b) (4)	15 Mar 2021 21:50:55
Signature has been broken.	Nancy Tang (b) (4)	15 Mar 2021 21:50:38
User entered 'ug (ug)' reason for change: Data Entry Error	Nancy Tang (b) (4)	15 Mar 2021 21:50:38
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 00:18:43
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'mg (mg)'	(b) (4) Son Do (b) (4)	25 Jan 2021 19:14:50

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	25 Jan 2021 19:14:50



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:13**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'once daily (QD)'	(b) (4) Son Do (b) (4)	25 Jan 2021 19:14:50

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	25 Jan 2021 19:14:50

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered 'Oral (ORAL)'	Son Do (b) (4)	25 Jan 2021 19:14:50

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered empty.	Son Do (b) (4)	25 Jan 2021 19:14:50

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '07 Jan 2021'	(b) (4) Son Do (b) (4)	25 Jan 2021 19:14:50

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered '0'	Son Do (b) (4)	25 Jan 2021 19:14:50

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered 'Yes (Y)'	Son Do (b) (4)	25 Jan 2021 19:14:50

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered empty.	Son Do (b) (4)	25 Jan 2021 19:14:50



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered 'No (N)'	Son Do (b) (4)	25 Jan 2021 19:14:50

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 19:14:50

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 19:14:50

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Jan 2021 19:14:50

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Jan 2021 23:46:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 23:46:03
Data point term sent to Coder	System	25 Jan 2021 19:15:45
User entered 'omeprazole'	Son Do (b) (4)	25 Jan 2021 19:15:38

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered 'No (N)'	Son Do (b) (4)	25 Jan 2021 19:15:38

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:13**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'nausea, med exposure'	(b) (4) Son Do (b) (4)	25 Jan 2021 19:15:38

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '20'	(b) (4) Son Do (b) (4)	25 Jan 2021 19:15:38



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'mg (mg)'	(b) (4) Son Do (b) (4)	25 Jan 2021 19:15:38

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	25 Jan 2021 19:15:38

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'once daily (QD)'	(b) (4) Son Do (b) (4)	25 Jan 2021 19:15:38

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	25 Jan 2021 19:15:38

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	25 Jan 2021 19:15:38

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	25 Jan 2021 19:15:38

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '07 Jan 2021'	(b) (4) Son Do (b) (4)	25 Jan 2021 19:15:38

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered '0'	(b) (4) Son Do (b) (4)	25 Jan 2021 19:15:38



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	25 Jan 2021 19:15:38

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered empty.	Son Do (b) (4)	25 Jan 2021 19:15:38

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'No (N)'	(b) (4) Son Do (b) (4)	25 Jan 2021 19:15:38

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 19:15:38

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 19:15:38

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Jan 2021 19:15:38

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: LAMOTRIGINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Jan 2021 19:17:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 19:17:50
Data point term sent to Coder	System	25 Jan 2021 19:16:46
User entered 'lamotrigine'	Son Do (b) (4)	25 Jan 2021 19:16:14

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered 'No (N)'	Son Do (b) (4)	25 Jan 2021 19:16:14



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:13**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered 'depression'	(b) (4) Son Do (b) (4)	25 Jan 2021 19:16:14

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered '25'	Son Do (b) (4)	25 Jan 2021 19:16:14

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered 'mg (mg)'	Son Do (b) (4)	25 Jan 2021 19:16:14

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered empty.	Son Do (b) (4)	25 Jan 2021 19:16:14

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered 'twice daily (BID)'	Son Do (b) (4)	25 Jan 2021 19:16:14

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
User entered empty.	(b) (4) Son Do (b) (4)	25 Jan 2021 19:16:14

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered 'Oral (ORAL)'	Son Do (b) (4)	25 Jan 2021 19:16:14

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered empty.	Son Do (b) (4)	25 Jan 2021 19:16:14



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered '01 Jun 2020'	Son Do (b) (4)	25 Jan 2021 19:16:14

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:13

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered '0'	Son Do (b) (4)	25 Jan 2021 19:16:14

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered 'Yes (Y)'	Son Do (b) (4)	25 Jan 2021 19:16:14

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered empty.	Son Do (b) (4)	25 Jan 2021 19:16:14

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:38:32
	(b) (4)	
User entered 'No (N)'	Son Do (b) (4)	25 Jan 2021 19:16:14

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Jan 2021 19:16:14

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 19:16:14

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Jan 2021 19:16:14



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:13:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Apr 2021 10:04:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:04:30
Data point term sent to Coder Coding entries removed.	System Colleen McLellan (b) (4)	06 Apr 2021 17:17:05 06 Apr 2021 17:16:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Mar 2021 08:04:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 08:04:24
Data point term sent to Coder	System	02 Mar 2021 01:05:18
Data point term sent to Coder	System	02 Mar 2021 00:31:03
User entered 'Guaifenesin (Extended Release)'	Nancy Tang (b) (4) (b) (4)	02 Mar 2021 00:30:06

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Yes (Y)'	Nancy Tang (b) (4)	02 Mar 2021 00:30:06

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:13:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User closed query 'Per CDM: Query responses on AE#1 and AE#3 indicates that this medication was taken for AEs #1 and #3; however, the start date of this medication (26 Feb 2021) is after the end date of AEs #1 and #3 (24 Feb 2021). Please review and verify dates and ensure the CM and AE pages are reconciled. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:01:30
Query 'Per CDM: Query responses on AE#1 and AE#3 indicates that this medication was taken for AEs #1 and #3; however, the start date of this medication (26 Feb 2021) is after the end date of AEs #1 and #3 (24 Feb 2021). Please review and verify dates and ensure the CM and AE pages are reconciled. Review and update as appropriate. ' answered with 'RECONCILED - INDICATION COUGH, AE LL 4' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 17:16:45
User entered 'COUGH' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	06 Apr 2021 17:16:18
User opened query 'Per CDM: Query responses on AE#1 and AE#3 indicates that this medication was taken for AEs #1 and #3; however, the start date of this medication (26 Feb 2021) is after the end date of AEs #1 and #3 (24 Feb 2021). Please review and verify dates and ensure the CM and AE pages are reconciled. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 09:50:21
User entered 'UNCONTROLLED NAUSEA AND COUGHING' reason for change: Data Entry Error	Nancy Tang (b) (4)	02 Mar 2021 01:04:40
User entered 'uncontrolled nausea and coughing.'	Nancy Tang (b) (4)	02 Mar 2021 00:30:06

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '600'	Nancy Tang (b) (4)	02 Mar 2021 00:30:06

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:13:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'mg (mg)'	Nancy Tang (b) (4)	02 Mar 2021 00:30:06

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 00:30:06

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:13:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'twice daily (BID)'	Nancy Tang (b) (4)	02 Mar 2021 00:30:06

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:13:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 00:30:06



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Oral (ORAL)'	Nancy Tang (b) (4)	02 Mar 2021 00:30:06

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:13:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 00:30:06

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '26 Feb 2021'	Nancy Tang (b) (4)	02 Mar 2021 00:30:06

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '0'	Nancy Tang (b) (4)	02 Mar 2021 00:30:06

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:13:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Colleen McLellan (b) (4)	05 Apr 2021 22:37:09
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Nancy Tang (b) (4)	02 Mar 2021 00:30:18
User entered 'No (N)'	Nancy Tang (b) (4)	02 Mar 2021 00:30:06

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:13:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '01 Apr 2021' reason for change: Data Entry Error	Colleen McLellan (b) (4)	05 Apr 2021 22:37:09
	(b) (4)	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	02 Mar 2021 00:30:18
User entered empty; reason for change Data Entry Error	Nancy Tang (b) (4)	02 Mar 2021 00:30:18
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	02 Mar 2021 00:30:06
User entered '07 Mar 2021'	Nancy Tang (b) (4)	02 Mar 2021 00:30:06

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:13:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'No (N)'	Nancy Tang (b) (4)	02 Mar 2021 00:30:06

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Mar 2021 00:30:06



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 00:30:06

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Mar 2021 00:30:06

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: VITAMIN B1 NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Mar 2021 17:56:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Mar 2021 17:56:09
Data point term sent to Coder	System	02 Mar 2021 00:50:09
User entered 'Vitamin B1'	Nancy Tang (b) (4) (b) (4)	02 Mar 2021 00:50:05

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Yes (Y)'	Nancy Tang (b) (4)	02 Mar 2021 00:50:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered 'RELAPSE OF RENAL CELL CARCINOMA METASTASIZED TO HIS LUNGS'	(b) (4) Nancy Tang (b) (4)	02 Mar 2021 00:50:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '100'	Nancy Tang (b) (4)	02 Mar 2021 00:50:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'mg (mg)'	Nancy Tang (b) (4)	02 Mar 2021 00:50:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 00:50:05



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'once daily (QD)'	Nancy Tang (b) (4)	02 Mar 2021 00:50:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 00:50:05

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Oral (ORAL)'	Nancy Tang (b) (4)	02 Mar 2021 00:50:05

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 00:50:05

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '26 Feb 2021'	Nancy Tang (b) (4)	02 Mar 2021 00:50:05

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '0'	Nancy Tang (b) (4)	02 Mar 2021 00:50:05

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Yes (Y)'	Nancy Tang (b) (4)	02 Mar 2021 00:50:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 00:50:05



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'No (N)'	Nancy Tang (b) (4)	02 Mar 2021 00:50:05

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 00:50:05

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 00:50:05

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Mar 2021 00:50:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:13:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Apr 2021 17:18:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 17:18:18
Data point term sent to Coder Coding entries removed.	System Colleen McLellan (b) (4)	06 Apr 2021 17:17:05 06 Apr 2021 17:16:56
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Mar 2021 09:50:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 09:50:15
Data point term sent to Coder User entered 'Benzonatate'	System Nancy Tang (b) (4)	02 Mar 2021 01:05:18 02 Mar 2021 01:04:23

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'No (N)'	Nancy Tang (b) (4)	02 Mar 2021 01:04:23

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:13:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'COUGH' reason for change: Data Entry Error	Colleen McLellan (b) (4)	06 Apr 2021 17:16:56
	(b) (4)	
User entered 'UNCONTROLLED NAUSEA AND COUGHING' reason for change: Data Entry Error	Nancy Tang (b) (4)	02 Mar 2021 01:04:51
User entered 'UNCONTROLLED NAUSEA AND COUGHING.'	Nancy Tang (b) (4)	02 Mar 2021 01:04:23

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '100'	Nancy Tang (b) (4)	02 Mar 2021 01:04:23



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:13:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'mg (mg)'	Nancy Tang (b) (4)	02 Mar 2021 01:04:23

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:13:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 01:04:23

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:13:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'three times daily (TID)'	Nancy Tang (b) (4)	02 Mar 2021 01:04:23

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:13:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 01:04:23

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Oral (ORAL)'	Nancy Tang (b) (4)	02 Mar 2021 01:04:23

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:13:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 01:04:23

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:13:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '26 Feb 2021'	Nancy Tang (b) (4)	02 Mar 2021 01:04:23

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '0'	Nancy Tang (b) (4)	02 Mar 2021 01:04:23



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Colleen McLellan (b) (4)	05 Apr 2021 22:38:20
	(b) (4)	
User entered 'Yes (Y)'	Nancy Tang (b) (4)	02 Mar 2021 01:04:23

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:13:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '01 Apr 2021' reason for change: Data Entry Error	Colleen McLellan (b) (4)	05 Apr 2021 22:38:20
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 01:04:23

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'No (N)'	Nancy Tang (b) (4)	02 Mar 2021 01:04:23

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Mar 2021 01:04:23

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 01:04:23

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Mar 2021 01:04:23

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:13:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Mar 2021 07:59:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 07:59:10
Data point term sent to Coder	System	02 Mar 2021 01:07:19
User entered 'Gabapentin'	Nancy Tang (b) (4) (b) (4)	02 Mar 2021 01:06:36

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:13:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'No (N)'	Nancy Tang (b) (4)	02 Mar 2021 01:06:36



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:13:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered 'RELAPSE OF RENAL CELL CARCINOMA METASTASIZED TO HIS LUNGS'	(b) (4) Nancy Tang (b) (4)	02 Mar 2021 01:06:36

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:13:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '300'	Nancy Tang (b) (4)	02 Mar 2021 01:06:36

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:13:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'mg (mg)'	Nancy Tang (b) (4)	02 Mar 2021 01:06:36

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:13:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 01:06:36

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:13:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'once daily (QD)'	Nancy Tang (b) (4)	02 Mar 2021 01:06:36

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:13:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 01:06:36

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Oral (ORAL)'	Nancy Tang (b) (4)	02 Mar 2021 01:06:36

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:13:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 01:06:36



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '26 Feb 2021'	Nancy Tang (b) (4)	02 Mar 2021 01:06:36

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '0'	Nancy Tang (b) (4)	02 Mar 2021 01:06:36

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Yes (Y)'	Nancy Tang (b) (4)	02 Mar 2021 01:06:36

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 01:06:36

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:13:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'No (N)'	Nancy Tang (b) (4)	02 Mar 2021 01:06:36

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 01:06:36

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 01:06:36

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Mar 2021 01:06:36



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:13:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Apr 2021 13:43:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 13:43:44
User closed query 'Per DM CLR: Please review the start/stop date of this CM as it overlaps with CM #18 within the same timeframe. Please confirm dates so there is no overlap, or remove duplicates as appropriate. Otherwise, confirm if both medications were taken at the same time. ' (Site from DM). Query 'Per DM CLR: Please review the start/stop date of this CM as it overlaps with CM #18 within the same timeframe. Please confirm dates so there is no overlap, or remove duplicates as appropriate. Otherwise, confirm if both medications were taken at the same time. ' answered with 'CM was taken and start/stop dates of the CM overlaps with CM#18 due to different dosages of same medication names were taken at the same time.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 09:33:29
Data point term sent to Coder Coding entries removed.	Nancy Tang (b) (4)	31 Mar 2021 18:00:11
	System	31 Mar 2021 17:59:31
	Nancy Tang (b) (4)	31 Mar 2021 17:58:33
User opened query 'Per DM CLR: Please review the start/stop date of this CM as it overlaps with CM #18 within the same timeframe. Please confirm dates so there is no overlap, or remove duplicates as appropriate. Otherwise, confirm if both medications were taken at the same time. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 12:39:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 07:59:10

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:13:13

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	02 Mar 2021 07:59:10
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	02 Mar 2021 01:08:19
User entered 'GABAPENTIN'	Nancy Tang (b) (4)	02 Mar 2021 01:08:06

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:13:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'No (N)'	Nancy Tang (b) (4)	02 Mar 2021 01:08:06

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:13:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'POSSIBLE RELAPSE OF RENAL CELL CARCINOMA METASTASIZED TO HIS LUNGS' reason for change: Data Entry Error	Nancy Tang (b) (4)	31 Mar 2021 17:58:33
User entered 'RELAPSE OF RENAL CELL CARCINOMA METASTASIZED TO HIS LUNGS'	Nancy Tang (b) (4)	02 Mar 2021 01:08:06

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:13:13**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '100'	Nancy Tang (b) (4)	02 Mar 2021 01:08:06

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:13:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'mg (mg)'	Nancy Tang (b) (4)	02 Mar 2021 01:08:06

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:13:13**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 01:08:06

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:13:13**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'once daily (QD)'	Nancy Tang (b) (4)	02 Mar 2021 01:08:06



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:13:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 01:08:06

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Oral (ORAL)'	Nancy Tang (b) (4)	02 Mar 2021 01:08:06

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:13:13**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 01:08:06

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '26 Feb 2021'	Nancy Tang (b) (4)	02 Mar 2021 01:08:06

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '0'	Nancy Tang (b) (4)	02 Mar 2021 01:08:06

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Yes (Y)'	Nancy Tang (b) (4)	02 Mar 2021 01:08:06

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:13:13**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 01:08:06

US3642076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:13:13**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'No (N)'	Nancy Tang (b) (4)	02 Mar 2021 01:08:06



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 01:08:06

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 01:08:06

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Mar 2021 01:08:06

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:13:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Mar 2021 11:40:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:40:49
Data point term sent to Coder	System	02 Mar 2021 01:09:20
User entered 'Methylprednisolone'	Nancy Tang (b) (4) (b) (4)	02 Mar 2021 01:09:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:13:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'No (N)'	Nancy Tang (b) (4)	02 Mar 2021 01:09:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:13:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered 'RELAPSE OF RENAL CELL CARCINOMA METASTASIZED TO HIS LUNGS'	(b) (4) Nancy Tang (b) (4)	02 Mar 2021 01:09:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:13:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '4'	Nancy Tang (b) (4)	02 Mar 2021 01:09:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:13:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'mg (mg)'	Nancy Tang (b) (4)	02 Mar 2021 01:09:05



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:13:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 01:09:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:13:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered 'once daily (QD)'	(b) (4) Nancy Tang (b) (4)	02 Mar 2021 01:09:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:13:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 01:09:05

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'Oral (ORAL)'	Nancy Tang (b) (4)	02 Mar 2021 01:09:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:13:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 01:09:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:13:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '26 Feb 2021'	Nancy Tang (b) (4)	02 Mar 2021 01:09:05

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '0'	Nancy Tang (b) (4)	02 Mar 2021 01:09:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:13:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry	Colleen McLellan (b) (4)	05 Apr 2021 22:39:14
Error	(b) (4)	
User entered 'Yes (Y)'	Nancy Tang (b) (4)	02 Mar 2021 01:09:05



US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:13:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered '01 Apr 2021' reason for change: Data Entry Error	Colleen McLellan (b) (4)	05 Apr 2021 22:39:14
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	02 Mar 2021 01:09:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:13:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
	(b) (4)	
User entered 'No (N)'	Nancy Tang (b) (4)	02 Mar 2021 01:09:05

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 01:09:05

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 01:09:05

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Mar 2021 01:09:05

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:13:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:51
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CHLORDIAZEPOXIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	02 Mar 2021 10:14:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	02 Mar 2021 10:14:21
Data point term sent to Coders	System	02 Mar 2021 01:12:21
User entered 'Chlordiazepoxide'	Nancy Tang (b) (4)	02 Mar 2021 01:11:52

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:13:13**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:51
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	02 Mar 2021 01:11:52

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:13:13**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:51
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered 'ANXIETY RELATED TO RELAPSE OF RENAL CELL CARCINOMA METASTASIZED TO HIS LUNGS'	(b) (4) Nancy Tang (b) (4)	02 Mar 2021 01:11:52



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:13:13**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:51
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered '25'	(b) (4) Nancy Tang (b) (4)	02 Mar 2021 01:11:52

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:13:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:51
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered 'mg (mg)'	(b) (4) Nancy Tang (b) (4)	02 Mar 2021 01:11:52

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:13:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:51
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Mar 2021 01:11:52

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:13:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:51
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered 'once daily (QD)'	(b) (4) Nancy Tang (b) (4)	02 Mar 2021 01:11:52

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:13:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:51
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Mar 2021 01:11:52

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:13:13**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:51
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered 'Oral (ORAL)'	(b) (4) Nancy Tang (b) (4)	02 Mar 2021 01:11:52

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:13:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:51
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered empty.	(b) (4) Nancy Tang (b) (4)	02 Mar 2021 01:11:52

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:13:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:51
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered '26 Feb 2021'	(b) (4) Nancy Tang (b) (4)	02 Mar 2021 01:11:52



**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:13:13**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:51
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered '0'	(b) (4) Nancy Tang (b) (4)	02 Mar 2021 01:11:52

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:13:13**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:51
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	02 Mar 2021 01:11:52

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:13:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:51
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered '28 Feb 2021'	(b) (4) Nancy Tang (b) (4)	02 Mar 2021 01:11:52

US3642076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:13:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:51
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered 'No (N)'	(b) (4) Nancy Tang (b) (4)	02 Mar 2021 01:11:52

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:13:13**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:51
User entered '1'	System	02 Mar 2021 01:11:52

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:51
User entered '1'	System	02 Mar 2021 01:11:52

**US3642076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:13:13**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:24:51
User entered '804 (804)'	System	02 Mar 2021 01:11:52

US3642076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:13:13

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:13:48
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:29:43
User closed query 'Concomitant procedures box is ticked as "Other action taken" for the SAEs "UNCONTROLLED NAUSEA AND COUGH" and "RELAPSE OF RENAL CELL CARCINOMA METASTASIZED TO HIS LUNGS ", please update the pages or clarify. Thanks!' (Site from CRA). Query 'Concomitant procedures box is ticked as "Other action taken" for the SAEs "UNCONTROLLED NAUSEA AND COUGH" and "RELAPSE OF RENAL CELL CARCINOMA METASTASIZED TO HIS LUNGS ", please update the pages or clarify. Thanks!' answered with 'updated per query request' (Site from CRA). Signature has been broken.	(b) (4) (b) (4), (b) (6) Nancy Tang (b) (4)	23 Mar 2021 21:29:06 15 Mar 2021 21:59:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Nancy Tang (b) (4)	15 Mar 2021 21:59:16
User opened query 'Concomitant procedures box is ticked as "Other action taken" for the SAEs "UNCONTROLLED NAUSEA AND COUGH" and "RELAPSE OF RENAL CELL CARCINOMA METASTASIZED TO HIS LUNGS ", please update the pages or clarify. Thanks!' (Site from CRA). User signature succeeded.	(b) (4), (b) (6) Stephen Spector (b) (4)	11 Mar 2021 11:04:49 13 Feb 2021 02:38:32
User entered 'No (N)'	Son Do (b) (4)	23 Sep 2020 16:44:15



US3642076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:13:13

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:30
	(b) (4)	
User entered '22 Feb 2021'	Nancy Tang (b) (4)	15 Mar 2021 22:06:45

US3642076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:13:13

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:30
	(b) (4)	
User entered 'CT SCAN OF ABDOMEN AND THE BRAIN' reason for change: Data Entry Error	Nancy Tang (b) (4)	15 Mar 2021 22:07:00
User entered 'CT Scan of abdomen'	Nancy Tang (b) (4)	15 Mar 2021 22:06:45

US3642076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:13:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:56
	(b) (4)	
Signature has been broken.	Nancy Tang (b) (4)	31 Mar 2021 18:44:29
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Nancy Tang (b) (4)	31 Mar 2021 18:44:29
	(b) (4)	
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:30
	(b) (4)	
User entered 'Adverse Event (AE)'	Nancy Tang (b) (4)	15 Mar 2021 22:06:45
	(b) (4)	

US3642076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:13:13

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:30
	(b) (4)	
User entered empty.	Nancy Tang (b) (4)	15 Mar 2021 22:06:45

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'USA-US109-2021-MRNA-1273-P301000007'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:18:04
User entered 'No (N)'	System	02 Mar 2021 15:15:50



**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

US3642076

Folder: SAE USA-US109-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Stephen'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Spector'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:27:32
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
User entered 'US'	(b) (4) System	02 Mar 2021 15:18:57

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Apr 2021 18:28:33
User entered '5'	System	16 Apr 2021 15:36:43
User entered '4'	System	07 Apr 2021 13:35:15
User entered '3'	System	16 Mar 2021 13:28:02
User entered '2'	System	15 Mar 2021 13:58:24
User entered '1'	System	02 Mar 2021 15:18:57



**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'USA-US109-2021-MRNA-1273-P301000007'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:18:04
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50



**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Stephen'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Spector'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:27:32
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
User entered 'US'	(b) (4) System	02 Mar 2021 15:18:57

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Apr 2021 18:28:33
User entered '5'	System	16 Apr 2021 15:36:43
User entered '4'	System	07 Apr 2021 13:35:15
User entered '3'	System	16 Mar 2021 13:28:02
User entered '2'	System	15 Mar 2021 13:58:24
User entered '1'	System	02 Mar 2021 15:18:57

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:13:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
User entered '02/Mar/2021 09:18'	(b) (4) System	02 Mar 2021 15:18:57

US3642076

Folder: SAE USA-US109-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:13:13

**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)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:27:32
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:57

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'USA-US109-2021-MRNA-1273-P301000007'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:15:50



**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:18:04
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Stephen'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Spector'	System	02 Mar 2021 15:15:50



**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:27:32
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
User entered 'US'	(b) (4) System	02 Mar 2021 15:18:57

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Apr 2021 18:28:33
User entered '5'	System	16 Apr 2021 15:36:43
User entered '4'	System	07 Apr 2021 13:35:15
User entered '3'	System	16 Mar 2021 13:28:02
User entered '2'	System	15 Mar 2021 13:58:24
User entered '1'	System	02 Mar 2021 15:18:57

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:13:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:30
User entered '15/Mar/2021 09:58'	(b) (4) System	15 Mar 2021 13:58:24

US3642076

Folder: SAE USA-US109-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:13:13

**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.	Stephen Spector (b) (4)	19 Mar 2021 23:55:30
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:27:32
User entered 'I'		15 Mar 2021 13:58:24

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'USA-US109-2021-MRNA-1273-P301000007'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:18:04
User entered 'No (N)'	System	02 Mar 2021 15:15:50



**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Stephen'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Spector'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:27:32
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
User entered 'US'	(b) (4) System	02 Mar 2021 15:18:57

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Apr 2021 18:28:33
User entered '5'	System	16 Apr 2021 15:36:43
User entered '4'	System	07 Apr 2021 13:35:15
User entered '3'	System	16 Mar 2021 13:28:02
User entered '2'	System	15 Mar 2021 13:58:24
User entered '1'	System	02 Mar 2021 15:18:57



**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:13:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:30
User entered '16/Mar/2021 09:27'	(b) (4) System	16 Mar 2021 13:28:02

US3642076

Folder: SAE USA-US109-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:13:13

**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.	Stephen Spector (b) (4)	19 Mar 2021 23:55:30
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:28:02

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'USA-US109-2021-MRNA-1273-P301000007'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:18:04
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50



**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Stephen'	System	02 Mar 2021 15:15:50

US3642076

Folder: SAE USA-US109-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:13:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Spector'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:27:32
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
User entered 'US'	(b) (4) System	02 Mar 2021 15:18:57

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Apr 2021 18:28:33
User entered '5'	System	16 Apr 2021 15:36:43
User entered '4'	System	07 Apr 2021 13:35:15
User entered '3'	System	16 Mar 2021 13:28:02
User entered '2'	System	15 Mar 2021 13:58:24
User entered '1'	System	02 Mar 2021 15:18:57

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:13:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered '07/Apr/2021 09:35'	(b) (4) System	07 Apr 2021 13:35:15

US3642076

Folder: SAE USA-US109-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:13:13

**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.	Stephen Spector (b) (4)	08 Apr 2021 23:54:01
User entered 'I'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:35:15



**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'USA-US109-2021-MRNA-1273-P301000007'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:18:04
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50



**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Stephen'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Spector'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:27:32
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
User entered 'US'	(b) (4) System	02 Mar 2021 15:18:57

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Apr 2021 18:28:33
User entered '5'	System	16 Apr 2021 15:36:43
User entered '4'	System	07 Apr 2021 13:35:15
User entered '3'	System	16 Mar 2021 13:28:02
User entered '2'	System	15 Mar 2021 13:58:24
User entered '1'	System	02 Mar 2021 15:18:57

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:13:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:02:00
User entered '16/Apr/2021 08:36'	(b) (4) System	16 Apr 2021 15:36:43

US3642076

Folder: SAE USA-US109-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:13:13

**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.	Stephen Spector (b) (4)	19 Apr 2021 18:02:00
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:36:43

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'USA-US109-2021-MRNA-1273-P301000007'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:15:50



**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:18:04
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Yes (Y)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'No (N)'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Stephen'	System	02 Mar 2021 15:15:50

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:18:38
User entered 'Spector'	System	02 Mar 2021 15:15:50



**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 13:27:32
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:33
User entered 'US'	(b) (4) System	02 Mar 2021 15:18:57

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:13**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	16 Apr 2021 18:28:33
User entered '5'	System	16 Apr 2021 15:36:43
User entered '4'	System	07 Apr 2021 13:35:15
User entered '3'	System	16 Mar 2021 13:28:02
User entered '2'	System	15 Mar 2021 13:58:24
User entered '1'	System	02 Mar 2021 15:18:57

**US3642076**

**Folder: SAE USA-US109-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 09:13:13**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:02:00
User entered '16/Apr/2021 11:28'	(b) (4) System	16 Apr 2021 18:28:33

US3642076

Folder: SAE USA-US109-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:13:13

**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.	Stephen Spector (b) (4)	19 Apr 2021 18:02:00
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:28:33